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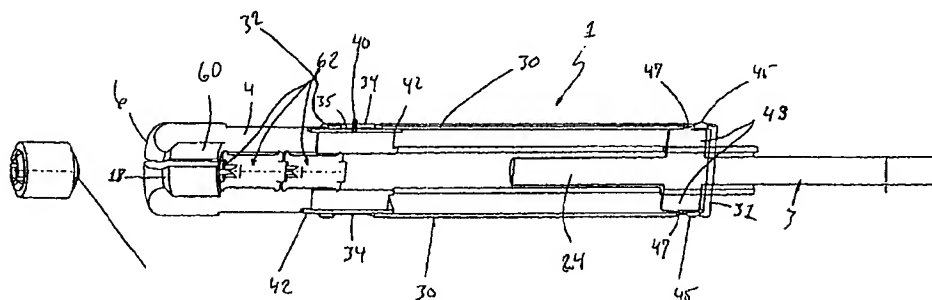
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(54) Title: SUTURE CLIPS, DELIVERY DEVICES AND METHODS



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(57) Abstract: Suture clips and suture clip loading, delivery, locking and severing devices in both catheter and endoscopic embodiments are disclosed that permit the delivery and application of suture clips directly in contact with or in close approximation to sutured tissue. The catheter or endoscopic versions incorporate a collet cage with a plurality of flexible collet fingers that captivate a suture clip ring and a suture clip plug for assembly with a suture. An outer sliding sleeve constrains the collet fingers when distally advanced to minimize potential trauma during delivery and assembly of the suture clip in close proximity to the stitched tissue. Proximal retraction of the sliding sleeve coupled with the distal advancement of a pusher against cam surfaces on the inner walls of the collet fingers causes the collet fingers to open. The catheter is designed to hold and assemble the suture clip in a first position and release the suture clip and sever the suture ends proximal to the suture clip in a second position. Single pusher two-step embodiments and double pusher three-step embodiments are disclosed. Suture clip designs with plugs having heads for use with the suture clip delivery catheter are also disclosed. A suture clip loading device for loading suture clip components into the delivery system as well as a threader for threading sutures into the suture clip systems are also disclosed. A method of loading, delivering and deploying suture clips is further disclosed.

SUTURE CLIPS, DELIVERY DEVICES AND METHODS

Field of the Invention

The disclosed invention relates generally to devices used to secure sutures. More particularly, the invention relates to suture clips and suture clip delivery devices used in conjunction with sewing devices used in flexible endoscopy; though it is also applicable to devices used in rigid endoscopy.

Background of the Invention

It is estimated that as many as 15,000,000 individuals in the United States suffer from stomach acid reflux into the lower esophageal region, commonly referred to as GERD (gastroesophageal reflux disorder). Although the illness may result from a wide variety of causes, it is ultimately the failure of the cardiac sphincter located above the stomach that enables a reflux event to occur. A surgical method developed to reduce reflux episodes involves forming tissue folds in the walls of the stomach to reduce the cross-sectional area of the gastroesophageal juncture to mimic the function of the cardiac sphincter. To perform these types of procedures, sewing devices used to suture the stomach wall into folds are used. The procedure typically involves a fiber optic endoscope introduced into the lower esophageal area. A sewing instrument is advanced down the working channel of the endoscope that has an aspiration port for generating negative pressure to suction stomach wall tissue into the sewing instrument where one or more sutures are implanted to hold the suctioned tissue in a folded condition known as a plication.

Sewing devices for this procedure are described in, for example, GB-A-2165559 and U.S. Pat. No. 5,080,663. According to these references, a sewing device is used for passing a thread through a tissue fold. The sewing device comprises a hollow needle movable between a first pre-tissue penetration position and a second position in which it passes through the tissue, with a thread carrier adapted to be attached to the thread and being receivable within the hollow needle.

Preferably, the sewing device comprises a body that defines a cavity within which the substrate portion can be held, for example, by means of suction. The hollow needle is mounted for movement in the body between the first and second positions. In some versions of the procedure, a suture is inserted into the tissue with a needle, the two ends of which are fed back out of the patient. Typically, a physician fashioned a series of half hitches to secure the suture to the subject tissue.

In other embodiments of the procedure, a tag attached to a distal end of the suture and contained within a lumen of the needle is inserted into and past the tissue. With the needle in an advanced position, i.e., with the needle distal tip extending distally beyond the pierced tissue, a pusher forces the tag out of the needle. After retraction of the needle from the tissue, the suture is retracted so that the tag contacts the tissue. The tag functions as an anchor that enables the suture to be secured to the tissue from the proximal end and also disperses the force applied to the tissue by the suture to prevent tearing of the tissue. Such a device and procedure is described in U.S. Patent No. 5,080,663 to Mills et al., the contents of which are incorporated herein by reference.

One of the significant problems associated with these procedures is the time and number of intubations needed to perform the various procedures endoscopically. Due to a number of concerns, a patient is typically anesthetized for no more than approximately 40 minutes. In this period of time, procedures such as the GERD procedure must be performed to completion. In the GERD procedure, several intubations are performed to create several plications. As many as nine intubations are required to create just one plication. This is the case when half hitches are used to secure the suture. Each half hitch requires the hitch to be made outside the endoscope and then advanced down the endoscope with a pusher. Typically, six half hitches are used per suture thus six intubations are needed to secure the half hitches. The time needed for each intubation substantially reduces the working time to complete a GERD procedure.

One approach to solving this problem is disclosed in U.S. Patent No. 5,584,861 to Swain. The Swain patent discloses a suture clip and suture clip delivery device that is used in place of half hitch knots. The disclosed suture clip is a cylinder with a plug that can be releasably secured in the cylinder. The disclosed suture clip delivery device includes a tube, the distal end of which has a recess for receiving the suture

clip. An axially movable stirrup is provided at the distal end that has the capacity to be moved from a first position that secures the suture clip to the tube and a second position that allows for the suture clip to be removed from the recess.

An aperture is provided in the cylinder to receive the suture. The cylinder is advanced over the suture that exits from a proximal end of the cylinder and enters the tube. An aperture in a sidewall of the tube provides egress for the suture. The plug is then advanced down the tube and into the cylinder. The interfacing walls of the cylinder and plug capture the suture. A pusher is used to force the plug into the cylinder while the stirrup maintains the suture clip in the recess. Following plug insertion, the stirrup, which is offset from the center axis of the tube, is advanced distally from the distal end of the tube to release the suture clip from the tube.

Although the Swain device solves the problem of multiple half hitches, the overall design of the device has certain drawbacks. First, to successfully join the cylinder to the plug to form the suture clip, the stirrup must be physically maintained in a retracted position while an opposing force is applied with a pusher to the plug. Second, the presence of the stirrup inevitably prevents the tube and therefore, the suture clip from being placed tight against the sutured tissue. This opens the possibility for slack to develop between the clip and the tissue, which can potentially lead to a relaxation of the desired tissue fold.

Suture anchors or clips and the means to deliver and secure them are quite common in the medical industry as they play a significant role in simplifying the tedious task of securing tissue previously accomplished by tying knots on sutures. Quite common are metallic twist tie, staples and various forms of plastic or metallic permanent or temporary mechanical means to prevent the suture from slipping through the tissue. As a result of their function, the clips are typically designed to be large to overcome the stresses expected of them. Disclosed are several single and multi-component suture clips as well as a variety of relatively simple compact suture clip delivery devices that can be inserted into a natural body orifice or through the working channel of an endoscope to cinch a suture clip into the desired position in close proximity to or against the plication.

It is to be appreciated that the suture clips and suture clip delivery devices disclosed herein have a potentially wide range of applications including, but not limited to, the attachment of devices, e.g., pH monitor to the gastrointestinal wall, the closure

of perforations or ulcers and the creation of anastomoses. Another useful application involves the use of radiopaque clips as fluoroscopic markers.

It is an object of the invention to provide a variety of suture clip designs that effectively disburse the forces applied to sutured tissue to prevent tearing. It is a further object of the invention to provide a suture clip delivery device that eliminates the need to manually apply opposing forces to construct a suture clip. Another object of the invention is to provide a suture clip delivery device that enables the user to place the clip tight against the sutured tissue to eliminate or at least minimize any slack development in the suture. A further object is to provide a suture-severing device that severs suture ends proximal to the suture clip. A still further object is to reduce the number of steps needed to assemble and cinch a suture clip and sever the excess suture material. These and other objects of the invention will become apparent from a reading of the following sections.

Summary of the Invention

One of the suture clip delivery and locking systems described herein includes a tool designed to be attached to the distal end of an endoscope or catheter among other possibilities. The tool has a body from which finger-like segments project distally. The finger-like projections are made of a material that allows the finger-like projections to flex or spring from a first closed position to a second open position and back to the first position. The finger-like projections define a chamber within which a suture clip is premounted or introduced by being advanced through the endoscope or catheter. The chamber is defined axially at a distal end by tangs extending radially inwardly from the distal ends of the finger-like projections and at a proximal end by proximal tangs or cam followers that extend radially inwardly from inner walls of the finger-like projections. A pusher, adapted to slide within the tool's body, is provided having a head that is adapted to mate with the cam follower to move the finger-like projections to the second open position when the pusher is advanced distally in and through the endoscope or catheter.

The suture clips described herein are designed to allow the suture to interwind through the clips in such a manner that the clips move with minimal friction while in an open position. In a closed position, the clip captures the suture, by the increased friction. The suture passes proximally through the chamber between the pusher head

and mating tang and then outward through a lumen in the chamber and continues proximally outside the endoscope or catheter to the proximal end of the entire system. The user may thread a suture through a clip and then load the clip into the tooling. The clip may, in certain designs, already be premounted and then require the final advance by the physician to the site. At the site the physician activates the handle to apply a force to the clip, thereby locking it to the suture. The application of force first secures the clip and captures the suture material within the mating surfaces, and then expels the clip from the tool to remain within the patient.

Suture clips disclosed herein include friction fit embodiments where the components of the clips capture the suture with friction, alignable finger embodiments that involve unaligned rails with apertures formed in each rail that provide a tortuous path for suture engagement that captures the suture and cylinder embodiments including locking cap embodiments, locking inner rod embodiments, inner wedge embodiments, opposing eyelets embodiments and wrapped cylinder embodiments that capture the suture with a mating semicircular sleeve.

The present invention pertains to improvements to an endoscopic suturing device such as that disclosed in U.S. patent nos. 5,792,153 and 5,080,663, the contents of which are incorporated by reference herein in their entirety. The improved suturing device and methods of the present application can be used to suture tissue internally via an endoscope for a wide variety of purposes such as: attaching a feeding tube to small intestine; closing intestinal openings in the case of a fistula, repairing esophageal tears and suturing tissue sites of localized bleeding. However, the invention is especially useful in the endoscopic suturing procedures to treat gastroesophageal reflux disease (GERD).

Another embodiment of the suture delivering, locking and severing systems described herein includes a multi-coaxial catheter with a three or four finger collet jaw affixed at a distal end. The catheter has a distal end from which the collet fingers distally project. The collet fingers are made of a material such as stainless steel or an engineering grade of plastic that allow the collet fingers to flex or spring from a pre-biased first open position to a second closed position and back to the first position. Alternatively, the collet fingers can be designed to flex or spring from a pre-biased first closed position to a second open position and back to the first position. The collet fingers define a cage within which a suture clip assembly is premounted. The cage is

defined proximally by a distal end of the collet body and distally by flanges extending radially inwardly from the distal ends of the collet fingers. The case is sized so that a plurality of suture clip plugs can be preloaded into the cage along with a single suture clip ring. By biasing the collet fingers in an open position, the need for cam surfaces and cam followers is eliminated.

In one embodiment, a single pusher, adapted to slide within the catheter body, is provided to engage loaded suture clip components and to disengage an outer sliding sleeve that is used to radially constrain the collet fingers into a closed position. In another embodiment, a separate control surface provided coaxially about the collet cage is employed to slide the outer sliding sleeve relative to the collet cage and the pusher.

With any of the embodiments, the outer sliding sleeve is provided to secure the collet fingers in a closed position when placed in a distally advanced position. The outer sliding sleeve performs the additional function of severing the suture at a point proximal to the suture clip after engagement of the suture upon proximal retraction. One or more suture slots are provided in the distal end of the outer sliding sleeve to provide suture exits. A distal end of the suture slots are sharpened to sever the suture. Upon proximal retraction of the outer sliding sleeve, the distal end of suture slot engages the suture and severs it when the distal end of the suture slot travels proximally to the proximal end of the collet fingers. Optionally, a fixed metallic ring can be affixed to the outer surface of the collet at a point proximal to the collet fingers and inside the outer sliding sleeve. The metallic ring is formed with a sharp distal tip that engages and severs the suture when the outer sliding sleeve is proximally retracted. The design enables the suture clip to be cinched in close proximity to the sutured tissue as well as allow for the severing of the suture tails and release of the suture from the delivery device in one step.

The suture clips designed for use with the referenced suture clip delivery systems are comprised of a plug and a ring that are configured to allow a suture to interwind through the clip in such a manner that the clip components move with minimal friction while in an open position. The plug is a headless design that has features that allow for a positive lock with the ring. Channels are provided in the plug to provide access ways for the suture to lessen the effort needed to thread the suture into the plug. The locking features of the plug are compressible so that when in a

locked state, the suture is captured via a combination of frictional engagement and the locking surfaces. The plugs have features built into their proximal and distal ends to allow stacking of the plugs to enhance alignment for the delivery of axial forces to set the plugs in rings. Additionally, a diverter for channeling the suture into axial slots formed in the plug is provided in one embodiment to extend distally of the distal end of the ring, when assembled with the plug, to interrogate the tissue and cause fibrosis. The fibrosis causes the tissue to become more bulky which is thought to enhance the therapeutic effect of this technique.

In another embodiment, the plug and ring are formed with inter-locking ribs or scales that enhance the advancement of the plug into the ring and prevent disengagement. The ribs are fashioned to allow one-way movement of the suture through the suture clip.

Once threaded into the ring and plug, the suture is passed through finger slots formed between adjacent collet fingers and out the suture slot of the outer sliding sleeve. This enables the suture tails to be channeled externally of the catheter for removal at the proximal end of the catheter outside the patient after the tails have been severed at a point proximal to the now assembled suture clip. The catheter operator may thread a suture through a clip and then load the clip into the tooling or thread the suture through a premounted clip. At the site the physician activates the handle to apply a force to the clip, thereby locking it to the suture. The application of force would first secure the clip components capturing the suture material within the mating surfaces, and then expel the clip from the tool to remain within the patient.

Suture clips disclosed herein include combination friction fit and positive locking embodiments where the components of the clips capture the suture with friction and lock the suture in place with inter-locking surfaces. It is to be appreciated that a wide variety of suture clip configurations can be formed from the basic ring/plug configuration that employs a friction fit/positive lock securing means.

A yet further suture locking and severing system described herein includes, in one general embodiment, a multi-coaxial catheter, and in a second general embodiment, a system dimensioned for use in the working channel of an endoscope. Each general embodiment has a two, three or four finger collet jaw affixed at a distal end. The collet jaw has a collet body from which the collet fingers distally project. The collet fingers are made of a material such as stainless steel or high modulus

plastics that allow the collet fingers to flex or spring from a first closed position to a second open position and back to the first position. Alternatively, the collet fingers can be designed to flex or spring from a first open position to a second closed position and back to the first position. This is accomplished by providing a radial bias in either the open or closed position. The collet fingers define a cage within which a suture clip assembly is premounted. The cage is defined proximally by a distal end of the collet body or by ramps formed on the inside walls of the collet fingers distal to the collet body and distally by flanges extending radially inwardly from the distal ends of the collet fingers. A further spatial restriction is provided toward the proximal end of the cage by the ramps that extend radially inwardly from the inner walls of the collet fingers and that additionally function as cams to open the collet fingers.

In one embodiment, a single pusher, adapted to slide within the catheter body, is provided to engage loaded suture clip components. In this embodiment, the collet fingers are biased in an open position. In another embodiment, a two-pusher system is employed that utilizes an inner pusher to secure a plug to a ring that together comprise the suture clip. A second pusher provided coaxially about, and in sliding engagement with, the inner pusher has a tapered distal end that interacts with the proximal ramps when advanced distally to cause the collet fingers to move from a closed position to an open position.

With any of the single or double pusher embodiments, an outer sliding sleeve can be provided to secure the collet fingers in a closed position when placed in a distally advanced position. The outer sliding sleeve performs the additional function of severing the suture at a point proximal to the suture clip after engagement of the suture. A suture slot is provided in the distal end of the outer sliding sleeve to provide a suture exit. Upon proximal retraction of the outer sliding sleeve, the distal end of the suture slot engages the suture and severs it when the distal end of the suture slot travels proximal to the proximal end of the collet fingers. Optionally, a fixed metallic ring can be affixed to the outer surface of the collet at a point proximal to the collet fingers and inside the outer sliding sleeve. The metallic ring is formed with a sharp distal tip that engages and severs the suture when the outer sliding sleeve is proximally retracted. The design enables the suture clip to be cinched in close proximity to the sutured tissue as well as allow for the severing of the suture tails and release of the suture from the delivery device in one step.

In yet a further embodiment, a head of the plug portion of the suture clip can be chamfered to engage the aforementioned ramps or ramps formed on the inner surfaces of the distal ends of the collet fingers to open the collet segments when a single pusher is distally advanced. This allows for the engagement of the plug and ring and release of the joined plug and ring in one step. The dimensions of the suture clip and collet segments are optimized to allow for full engagement of the plug and ring prior to clip release from the delivery device.

The suture clips designed for use with the suture clip delivery system are comprised of a plug and a ring that are configured to allow a suture to inter-wind through the clip in such a manner that the clips move with minimal friction while in an open position. In a closed position, the clip captures the suture by frictional engagement. Once threaded into the ring and plug, the suture is passed through finger slots formed between adjacent collet fingers and out the suture slot of the outer sliding sleeve. This enables the suture tails to be channeled externally of the catheter for removal at the proximal end of the catheter outside the patient after the tails have been severed at a point proximal to the now assembled suture clip. The catheter operator may thread a suture through a clip and then load the clip into the tooling or thread the suture through a premounted clip. After positioning the delivery system at the sutured tissue site, the device operator activates the handle to apply a force to the clip, thereby locking it to the suture. The application of force first secures the clip components thus capturing the suture material within the mating surfaces, and second expels the clip from the delivery system tool to remain within the patient.

Suture clips disclosed herein include friction fit embodiments where the components of the clips capture the suture with friction. It is to be appreciated that a wide variety of suture clip configurations can be formed from the basic ring/plug configuration that employs a friction fit securing means. Of course, the ring and plug components of the clip can be provided with interlocking features for enhancing the suture capturing effect.

In a still further embodiment, a suture clip delivery device having pivoting collet fingers is disclosed. The collet fingers rotate about a pin secured to a collet cage body. A pusher, suture clip component or other component radially restrains the pivoting collet fingers from pivoting radially outwardly at a distal end when proximal to a cinched position. Another embodiment employs a ring secured about the collet

cage body. A distal edge of the ring provides a pivot point and eliminates the need to secure the pivoting collet fingers to the collet cage with pins.

Also disclosed is a suture clip loader used to deliver the suture clip components into the collet cage. The suture clip loader has two main components, a main body through which a hypotube is secured and a plunger comprising a plunger head and a plunger rod. The plunger rod is dimensioned to slide freely within the hypotube. A suture clip ring is placed over a first end of the hypotube that is situated within a cavity formed in the loader main body. The distal end of a suture clip plug is loosely fit within the lumen of the first end for delivery into a collet cage. A collet cage with the collet fingers in an open position is advanced over the plug, hypotube and ring. Advancement of the plunger into the hypotube from a second hypotube end causes disengagement of the suture clip plug into the collet cage. The collet cage fingers are then moved into a closed position by advancing the outer sliding sleeve so as to grasp the suture clip ring that is retained in the collect cage when the collet cage is removed from the hypotube

Brief Description of the Drawings

FIG. 1 is a side partial cutaway sectional view of an endoscope with an attached suture clip delivery/locking device and suture clip in a first position according to one embodiment of the invention.

FIG. 1a is a perspective view of a suture clip delivery/locking device and suture clip in a first position according to another embodiment of the invention.

FIG. 1b is a perspective view of a suture clip delivery/locking device and suture clip in an intermediate position according to another embodiment of the invention.

FIG. 1c is a perspective view of a suture clip delivery/locking device and suture clip in an advanced intermediate position according to another embodiment of the invention.

FIG. 1d is a perspective view of a suture clip delivery/locking device and suture clip in an second open position according to another embodiment of the invention.

FIG. 2a is a side elevational view of a catheter with an attached suture clip delivery device and suture clip according to one embodiment of the invention.

FIG. 2b is a perspective view of a suture clip delivery/locking device and suture clip components in a pre-cinched state according to one embodiment of the invention.

FIG. 2c is a partial sectional view of a suture clip delivery/locking device and suture clip components in a pre-cinched state according to one embodiment of the invention.

FIG. 2d is a partial sectional view of a suture clip delivery/locking device and suture clip components in a partially cinched state according to one embodiment of the invention.

FIG. 2e is a partial sectional view of a suture clip delivery/locking device and suture clip components in a cinched, delivered state according to one embodiment of the invention.

FIG. 3d is a partial sectional view of a suture clip delivery/locking device and suture clip components in a pre-cinched state according to one embodiment of the invention.

FIG. 3 is a side partial cutaway view of an endoscope with an attached suture clip delivery/locking device and suture clip in a second position according to one embodiment of the invention.

FIG. 4 is a perspective view of a suture clip delivery/locking device and suture clip according to one embodiment of the invention.

FIG. 4a is a perspective view of a suture clip delivery/locking device and suture clip according to one embodiment of the invention.

FIG. 5 is a side elevational view of a plication with a suture clip attached to a suture according to one embodiment of the invention.

FIG. 6 is a perspective view of a suture clip assembly in an open position according to one embodiment of the invention.

FIG. 7 is a perspective view of a suture clip assembly in a closed position according to one embodiment of the invention.

FIG. 8 is a perspective view of a suture clip assembly in an open position according to another embodiment of the invention.

FIG. 8a is a fragmented side view of a suture clip assembly according to one embodiment of the invention.

FIG. 9 is a perspective view of a suture clip assembly in a partially closed position according to a further embodiment of the invention.

FIG. 10 is a perspective view of a suture clip assembly in a partially closed position according to one embodiment of the invention.

FIG. 11 is a side elevational view of a suture clip assembly in an open position according to another embodiment of the invention.

FIG. 12 is a side elevational view of a suture clip assembly in a closed position according to one embodiment of the invention.

FIG. 13 is a top view of a suture clip assembly according to one embodiment of the invention.

FIG. 14 is a perspective view of a suture clip assembly according to a further embodiment of the invention.

FIG. 15 is a side elevational view of a suture clip assembly in a closed position according to a further embodiment of the invention.

FIG. 16 is a side elevational view of a suture clip assembly in a partially closed position according to another embodiment of the invention.

FIG. 17 is a side elevational view of a suture clip assembly in a closed position according to another embodiment of the invention.

FIG. 18 is a perspective view of a suture clip assembly in a closed initial position according to another embodiment of the invention.

FIG. 19 is an end elevational view of a suture clip assembly in a closed initial position according to one embodiment of the invention.

FIG. 20 is an end elevational view of a suture clip assembly in a closed initial position according to a further embodiment of the invention.

FIG. 21 is an end elevational view of a suture clip assembly in a closed initial position according to one embodiment of the invention.

FIG. 22 is an end elevational view of a suture clip assembly in a closed initial position according to one embodiment of the invention.

FIG. 23 is a side elevational view of a suture clip assembly in an open position according to one embodiment of the invention.

FIG. 24 is an end view of a suture clip assembly and outer tube according to one embodiment of the invention.

FIG. 25 is an end elevational view of a suture clip assembly according to one embodiment of the invention.

FIG. 26 is an end elevational view of a suture clip assembly according to another embodiment of the invention.

FIG. 27 is an end elevational view of a suture clip assembly according to a further embodiment of the invention.

FIG. 28 is a side elevational view of a suture clip assembly according to a yet further embodiment of the invention.

FIG. 29 is an end elevational view of a suture clip assembly and outer tube according to one embodiment of the invention.

FIG. 30 is a side elevational view of suture clip assembly and outer tube according to another embodiment of the invention.

FIG. 31 is a side elevational view of a suture clip assembly and outer tube according to a further embodiment of the invention.

FIG. 32 is a side elevational view of a suture clip assembly and outer tube according to a yet further embodiment of the invention.

FIG. 33 is a perspective view of a suture clip assembly and outer tube according to one embodiment of the invention.

FIG. 34 is a perspective view of a suture clip assembly and outer tube according to one embodiment of the invention.

FIG. 35 is a side elevational view of a suture clip delivery tube and suture clip according to one embodiment of the invention.

FIG. 36 is a perspective view of a delivery tube with mounted suture clip before delivery of the suture clip to the desired site according to one embodiment of the invention.

FIG. 37 is a perspective view of a delivery tube with mounted suture clip during delivery of the suture clip according to one embodiment of the invention.

FIG. 38 is a perspective view of a delivery tube being retracted from a suture clip delivery site according to one embodiment of the invention.

FIG. 39 is a perspective view of a suture clip comprising a cylinder and cylinder cap according to one embodiment of the invention.

FIG. 40 is a sectional view of a partially engaged cylinder/cylinder cap suture clip assembly according to one embodiment of the invention.

FIG. 41 is a sectional view of an engaged cylinder/cylinder cap suture clip assembly according to one embodiment of the invention.

FIG. 42 is a perspective view of an unassembled cylinder/cylinder cap suture clip assembly according to one embodiment of the invention.

FIG. 43 is a perspective view of an assembled cylinder cap/cylinder suture clip assembly according to one embodiment of the invention.

FIG. 44 is a side sectional view of a cylinder cap/cylinder suture clip assembly preloaded in a delivery device according to one embodiment of the invention.

FIG. 45 is a front sectional view of a cylinder cap/cylinder suture clip assembly preloaded in a delivery device according to one embodiment of the invention.

FIG. 46 is a perspective view of an unassembled cylinder/locking rod suture clip assembly according to another embodiment of the invention.

FIG. 47 is a perspective view of an assembled cylinder/locking rod suture clip assembly according to another embodiment of the invention.

FIG. 48 is a perspective view of an unassembled slotted cylinder/locking rod suture clip assembly according to a further embodiment of the invention.

FIG. 49 is a perspective view of an assembled slotted cylinder/locking rod suture clip assembly according to a further embodiment of the invention.

FIG. 50 is a perspective view of an unassembled eyelet-bearing cylinder/locking rod suture clip assembly according to a still further embodiment of the invention.

FIG. 51 is a perspective view of an assembled eyelet-bearing cylinder/locking rod suture clip assembly according to a still further embodiment of the invention.

FIG. 52 is a perspective view of an unassembled dual cylinder suture clip assembly according to a yet further embodiment of the invention.

FIG. 53 is a perspective view of an assembled dual cylinder suture clip assembly according to a yet further embodiment of the invention.

FIG. 54 is a perspective view of an assembled dual cylinder suture clip assembly cinched to a plication according to a yet further embodiment of the invention.

FIG. 55 is a perspective view of an unassembled dual cylinder suture clip assembly having sidewall apertures according to yet another embodiment of the invention.

FIG. 56 is a perspective view of a partially assembled dual cylinder suture clip assembly having sidewall apertures according to yet another embodiment of the invention.

FIG. 57 is a perspective view of an assembled dual cylinder suture clip assembly having sidewall apertures according to yet another embodiment of the invention.

FIG. 58 is a front perspective view of a single cylinder suture clip assembly with sidewall apertures according to still another embodiment of the invention.

FIG. 59 is a side perspective view of a single cylinder suture clip assembly with sidewall apertures according to still another embodiment of the invention.

FIG. 60 is a perspective view of a partially assembled dual cylinder suture clip assembly having a locking jaw according to a further embodiment of the invention.

FIG. 61 is a perspective view of an assembled dual cylinder suture clip assembly having a locking jaw according to a further embodiment of the invention.

FIG. 62 is a side elevational view of a cylinder suture clip assembly component having a locking jaw according to a further embodiment of the invention.

FIG. 63 is a perspective view of a cylinder suture clip assembly component having a locking jaw according to a further embodiment of the invention.

FIG. 64 is a perspective view of an unlocked three tab suture clip according to a still further embodiment of the invention.

FIG. 65 is a perspective view of a locked three tab suture clip according to a still further embodiment of the invention.

FIG. 66 is a perspective view of a cylinder suture clip having a rotatable flap according to a yet further embodiment of the invention.

FIG. 67 is a partial sectional, perspective view of an unassembled cylinder/hollow rod suture clip assembly with the cylinder having a rotatable flap according to a yet further embodiment of the invention.

FIG. 68 is a sectional view of an assembled cylinder/hollow rod suture clip assembly with the cylinder having a secured rotatable flap according to a yet further embodiment of the invention.

FIG. 69 is a side sectional view of an unassembled sphere-shaped wedge/cylinder suture clip assembly according to another embodiment of the invention.

FIG. 70 is a side sectional view of an assembled sphere-shaped wedge/cylinder suture clip assembly according to another embodiment of the invention.

FIG. 71 is a side sectional view of a conical wedge/cylinder suture clip assembly according to yet another embodiment of the invention.

FIG. 72 is a side sectional view of an assembled bulbous plug/cylinder suture clip assembly according to a further embodiment of the invention.

FIG. 73 is a side sectional view of an assembled sphere-shaped plug/cylinder suture clip assembly with the cylinder having an annular inner channel according to a still further embodiment of the invention.

FIG. 74 is a perspective view of an unassembled wedge/cone suture clip assembly according to another embodiment of the invention.

FIG. 75 is a sectional view of an assembled wedge/cone suture clip assembly according to another embodiment of the invention.

FIG. 76 is a side sectional view of an unassembled tapered wedge/cylinder suture clip assembly according to yet another embodiment of the invention.

FIG. 77 is a side sectional view of an assembled tapered wedge/cylinder suture clip assembly according to yet another embodiment of the invention.

FIG. 78 is a perspective view of an assembled tapered wedge/cylinder suture clip assembly with a slot in the cylinder according to a further embodiment of the invention.

FIG. 79 is a side sectional view of an unassembled domed, flanged plug/cylinder suture clip assembly according to a still further embodiment of the invention.

FIG. 80 is a side sectional view of an assembled domed, flanged plug/cylinder suture clip assembly according to a still further embodiment of the invention.

FIG. 81 is a perspective view of a cylinder component with a slot according to a further embodiment of the invention.

FIG. 82 is a perspective view of a tapered wedge/cylinder suture clip assembly with a slot in the side of the cylinder according to a further embodiment of the invention.

FIG. 83 is a perspective view of an assembled tapered rod/cylinder suture clip assembly according to a further embodiment of the invention.

FIG. 84 is a side sectional view of a tapered wedge/cylinder suture clip assembly in a delivery device according to a further embodiment of the invention.

FIG. 85 is a perspective view of an unassembled rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 86 is a perspective view of a partially assembled rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 87 is a front view of an unassembled rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 88 is a perspective view of an unlocked joined rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 89 is a perspective view of a locked joined rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 90 is a side sectional view of an unlocked rod/half-sleeve suture clip assembly in a delivery device according to another embodiment of the invention.

FIG. 91 is a perspective view of a partially locked joined rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 92 is a front perspective view of a partially locked joined rod/half-sleeve suture clip assembly according to another embodiment of the invention.

FIG. 93 is a perspective view of a partially locked joined rod/half-sleeve suture clip assembly with the half-sleeve having a suture aperture according to a further embodiment of the invention.

FIG. 94 is a side elevational view of a locked joined rod/half-sleeve suture clip assembly with the half-sleeve having a suture aperture according to a further embodiment of the invention.

FIG. 95 is a front view of a locked joined rod/half-sleeve suture clip assembly with the half-sleeve having a suture aperture according to a further embodiment of the invention.

FIG. 96 is a perspective view of an unassembled rod/half-sleeve suture clip assembly with the half-sleeve having a suture aperture according to a yet further embodiment of the invention.

FIG. 97 is an end view of an unassembled rod/half-sleeve suture clip assembly according to a yet further embodiment of the invention.

FIG. 98 is an end view of a partially assembled rod/half-sleeve suture clip assembly according to a yet further embodiment of the invention.

FIG. 99 is an end view of an assembled and cinched rod/half-sleeve suture clip assembly according to a yet further embodiment of the invention.

FIG. 100 is an end view of an assembled rod/half-sleeve suture clip assembly according to a yet further embodiment of the invention.

FIG. 101 is a front view of a joined rod/half-sleeve suture clip assembly according to a yet further embodiment of the invention.

FIG. 102 is a perspective view of an unassembled rod/clamping jaw suture clip assembly according to a still further embodiment of the invention.

FIG. 103 is a side sectional view of an assembled mesh plug/rigid ring suture clip assembly according to one embodiment of the invention.

FIG. 104 is a side sectional view of a mesh plug delivery catheter with a mesh plug positioned within adjacent to a rigid ring and an expanded mesh plug according to one embodiment of the invention.

FIG. 105 is a side sectional view of a mesh plug suture clip component according to one embodiment of the invention.

FIG. 106 is a side sectional view of an undeployed mesh plug of mesh plug/rigid ring suture clip assembly with the mesh plug positioned in a delivery catheter positioned within a suture clip delivery device.

FIG. 107 is a side sectional view of an undeployed mesh plug of a mesh plug/rigid ring suture clip assembly with the mesh plug positioned in a delivery catheter positioned within the ring.

FIG. 108 is a side sectional view of a partially deployed mesh plug of a mesh plug/rigid ring suture clip assembly positioned in a delivery device including a mesh delivery catheter with pusher according to another embodiment of the invention.

FIG. 109 is a side sectional view of an assembled mesh plug/rigid ring suture clip assembly according to another embodiment of the invention.

FIG. 110 is a side sectional view of an assembled ribbon plug/rigid ring suture clip assembly according to a yet another embodiment of the invention.

FIG. 111 is a side view of a ribbon plug suture clip component according to a yet another embodiment of the invention.

FIG. 112 is a side sectional view of a partially assembled ribbon plug/rigid ring suture clip assembly according to a yet another embodiment of the invention.

FIG. 113 is a side sectional view of an assembled mesh plug/rigid ring suture clip assembly according to a yet another embodiment of the invention.

FIG. 114 is a side sectional view of an assembled channeled plug/ribbon ring suture clip assembly according to a further embodiment of the invention.

FIG. 115 is a side view of a ribbon ring suture clip component according to a further embodiment of the invention.

FIG. 116 is a side view of a ribbon ring suture clip component in a relaxed reduced diameter state according to a further embodiment of the invention.

FIG. 117 is a side view of a ribbon ring suture clip component in a stretched state according to a further embodiment of the invention.

FIG. 118 is a side elevational view of a channeled plug suture clip component according to a further embodiment of the invention.

FIG. 119 is a side elevational view of an assembled channeled plug/ribbon ring suture clip assembly according to a further embodiment of the invention.

FIG. 120 is a side view of an assembled barbell plug/mesh ring suture clip assembly according to a yet further embodiment of the invention.

FIG. 121 is a partial cutaway side perspective view of a single pusher suture clip delivering, locking and severing catheter distal end with a pre-mounted suture clip ring and three stacked suture clip plugs according to one embodiment of the invention.

FIG. 122 is a side perspective view of a single pusher suture clip delivering, locking and severing catheter distal end according to one embodiment of the invention.

FIG. 123 is a fragmentary partial sectional side perspective view of a single suture clip delivering, locking and severing catheter distal end with a single suture clip plug and without a loaded suture clip ring according to one embodiment of the invention.

FIG. 124 is a partial sectional side perspective view of a single pusher suture clip locking and severing catheter distal end with an assembled suture clip and two stacked suture clip plugs according another embodiment of the invention.

FIG. 125 is fragmentary side perspective view of a single pusher suture clip locking and severing catheter distal end showing a pusher and sliding sleeve locking features according to one embodiment of the invention.

FIG. 126 is a side sectional view of a single pusher suture clip delivering, locking and severing catheter with a sliding sleeve finger pull according to one embodiment of the invention.

FIG. 127 is a side perspective view of a suture clip plug according to one embodiment of the invention.

FIG. 128 is a bottom perspective view of a suture clip plug according to one embodiment of the invention.

FIG. 129 is a side sectional perspective view of a suture clip plug according to one embodiment of the invention.

FIG. 130 is a side perspective view of a suture clip assembled to a suture according to one embodiment of the invention.

FIG. 131 is a side sectional view of a suture clip assembly with rib formations according to one embodiment of the invention.

FIG. 132 is a perspective view of a collet cage assembly according to another embodiment of the invention.

FIG. 133 is a side sectional view of a collet cage assembly according to another embodiment of the invention.

FIG. 134 is a partial cutaway side perspective view of a double pusher suture clip locking and severing catheter distal end with a pre-mounted suture clip assembly according to one embodiment of the invention.

FIG. 135 is a partial sectional front perspective view of a double pusher suture clip locking and severing catheter distal end with a pre-mounted suture clip assembly according to one embodiment of the invention.

FIG. 136 is a partial sectional top perspective view of a double pusher suture clip locking and severing catheter distal end with an outer sliding sleeve partially retracted according to one embodiment of the invention.

FIG. 137 is a partial sectional front perspective view of a double pusher suture clip locking and severing catheter distal end according another embodiment of the invention.

FIG. 138 is back perspective view of a double pusher suture clip locking and severing catheter distal end and partial hypotube body according to one embodiment of the invention.

FIG. 139 is a side perspective view of a double pusher suture clip locking and severing catheter according to one embodiment of the invention.

FIG. 140 is a partial cutaway side perspective view of a double pusher suture clip locking and severing catheter distal end with loaded and threaded suture clip components according to one embodiment of the invention.

FIG. 141 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with pre-loaded suture clip components according to one embodiment of the invention.

FIG. 142 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with an inner pusher in an advanced position and a suture clip in a cinched condition according to one embodiment of the invention.

FIG. 143 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with an outer sliding sleeve in a partially retracted position according to one embodiment of the invention.

FIG. 144 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with an outer sliding sleeve in a fully retracted position according to one embodiment of the invention.

FIG. 145 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with an outer pusher in an advanced position engaging and opening collet fingers according to one embodiment of the invention.

FIG. 146 is a side sectional view of a double pusher suture clip locking and severing catheter distal end with a suture clip being released from a collet cage according to one embodiment of the invention.

FIG. 147 is an side sectional view of a single pusher suture clip locking and severing catheter distal end loaded with a suture clip plug and suture clip ring according to another embodiment of the invention.

FIG. 148 is a side sectional view of a single pusher suture clip locking and severing catheter distal end loaded with a convex head suture clip plug and suture clip ring according to one embodiment of the invention.

FIG. 149 is a top perspective view of an assembled suture lock plug and suture lock ring according to another embodiment of the invention.

FIG. 150 is a sectional view of an assembled suture lock plug and suture lock ring according to a further embodiment of the invention.

FIG. 151 is an end view of an assembled suture lock plug and suture lock ring according to a further embodiment of the invention.

FIG. 152 is a perspective view of an unassembled suture lock plug and suture lock ring according to a further embodiment of the invention.

FIG. 153 is a perspective view of a suture lock plug according to a yet further embodiment of the invention.

FIG. 154 is a side sectional view of a suture clip loading device according to one embodiment of the invention.

FIG. 155 is an end view of a suture clip loading device according to one embodiment of the invention.

FIG. 156 is a perspective view of an unassembled suture clip loading device according to one embodiment of the invention.

FIG. 157 is a side sectional view of a control handle according to a further embodiment of the invention.

FIG. 158 is a side sectional view of a control handle according to a yet further embodiment of the invention.

FIG. 159 is a plan view of a single action control handle according to a still further embodiment of the invention.

FIG. 160 is a sectional view of a single action control handle according to a still further embodiment of the invention.

FIG. 161 is a partial sectional view of a single action control handle according to a still further embodiment of the invention.

FIG. 162 is a partial sectional view of a single action control handle according to a still further embodiment of the invention.

FIG. 163 is a side sectional view of a single pusher suture clip locking and severing collet cage according to a further embodiment of the invention.

FIG. 164 is a side sectional view of a single pusher suture clip locking and severing collet cage according to a yet further embodiment of the invention.

FIG. 165 is a side sectional view of a single pusher suture clip locking and severing collet cage with a pre-cinched suture clip assembly according to a still further embodiment of the invention.

FIG. 166 is a top perspective sectional view of a single pusher suture clip locking and severing device according to a still further embodiment of the invention.

FIG. 167 is a side sectional view of a single pusher suture clip locking and severing collet cage with a cinched suture clip assembly according to a still further embodiment of the invention.

FIG. 168 is a front perspective view of a single pusher suture clip locking and severing device according to a still further embodiment of the invention.

FIG. 169 is a side sectional view of a single pusher suture clip locking and severing device with a cinched suture clip assembly and a pivot ring according to yet another embodiment of the invention.

FIG. 170 is a side perspective view of a collet cage body according to a still further embodiment of the invention.

FIG. 171 is a top perspective view of a collet cage body according to a still further embodiment of the invention.

FIG. 172 is a front elevational view of a collet cage body according to a still further embodiment of the invention.

FIG. 173 is a side sectional view of a threader according to one embodiment of the invention.

FIG. 174 is an end view of a threader according to one embodiment of the invention.
FIG. 175 is a perspective view of a threader according to one embodiment of the invention.

FIG. 176 is a side sectional view of a vacuum-actuated threader according to another embodiment of the invention.

FIG. 177 is a front elevational view of a vacuum-actuated threader according to another embodiment of the invention.

FIG. 178 is a side sectional view of a vacuum-actuated threader according to a further embodiment of the invention.

FIG. 179 is a front elevational view of a vacuum-actuated threader according to a further embodiment of the invention.

Detailed Description of the Preferred Embodiment

Referring to FIGS. 1-3, a clip delivery/locking device is shown generally as **1**. Device **1** is shown in an embodiment designed for mounting to the distal end of an endoscope **18**. Device **1** is generally cylindrical in shape and has a flange **17** extending proximally from a proximal end of device **1**. Flange **17** is adapted to conform to the contours of the exterior surface of endoscope **18**. The combination of the proximal end of device **1** interfacing with the distal end of endoscope **18** and flange **17** interfacing with the exterior surface of endoscope **18** effectively locks device **1** to endoscope **18**. Alternatively, device **1** can be secured to endoscope **18** with mechanical fasteners.

Device **1** has portions defining a clip holding chamber **4**. A proximal end **4a** of holding chamber **4** (shown in FIG. 4) formed on the proximal end of device **1** communicates with holding chamber **4** and a working channel **15** of endoscope **18**. Extending distally from a distal end of device **1** are fingers **9** that are oriented on opposite sides of, and partially define, holding chamber **4**. Fingers **9** are designed to flex or spring from a first position (shown in FIG. 1) to a second position (shown in FIG. 3) to deliver a suture clip assembly comprising in the illustrated embodiment, a plug **3** and a ring **8**. After delivery, fingers **9** spring back to the first position to receive another suture clip assembly. Preferably four fingers **9** are provided (as shown in FIG. 4a) although as little as two fingers **9** are needed. When viewing the distal end of device **1**, the distal ends of fingers **9** preferably form a segmented 360° ring.

Fingers **9**, in a preferred embodiment, have tapered finger ends **2** with the taper preferably increasing radially outwardly from a proximal end to a distal end of finger ends **2**. The proximal ends of finger ends **2** extend radially inwardly of the inner walls of fingers **9** to form distal tangs **12**. Distal tangs **12** provide a stop surface against which suture clip **3** can be compressed for manipulation as described in detail below and by which premature release of suture clip **3** is prevented.

Extending radially inwardly from fingers **9** from a point distal to distal tangs **12** are proximal tangs **13**. Proximal tangs **13** are preferably tapered with the taper increasing radially inwardly from a proximal end to a distal end of proximal tangs **13**. In an alternate embodiment shown in FIGS. 1a-1d, proximal tangs **13** are radiused portions of the inner walls of fingers **9** that merge into finger ends **2**. As described in more detail below, proximal tangs **13** facilitate the movement of fingers **9** from the first position to the second position and act as a cam follower to distal tangs **12**.

A pusher **14** is dimensioned and adapted to move freely in an axial direction with the working channel of endoscope **18** and within delivery device **1**. Pusher **14** preferably has a frusto-conically shaped distal end **19**, the tapered sides of which are dimensioned to contact proximal tangs **13** and translate distal axial movement into radial outward movement of fingers **9**.

An alternative to the delivery device shown in FIGS. 1 and 2a is shown in FIGS. 2b – 2e. This alternate embodiment can be used with an endoscope or independently as a catheter. In this embodiment, pusher **14** has a reduced diameter, substantially cylindrical distal end **19a**. The transition from the diameter of a main body of pusher **14** and distal end **19** forms tapered pusher surface **19b** dimensioned to contact proximal tangs **13** to affect the translation of distal axial motion of pusher **14** into radial outward motion of fingers **9**. With this embodiment, sutures **7** are severed at shoulder **9a** formed at the transition of the main body of delivery device **1** and proximal tangs **13** when tapered pusher surface **19b** contacts and slides along proximal tangs **13**.

To operate device **1**, a suture clip assembly **3a** (plug **3** and ring **8**), is advanced down endoscope working channel **15** in an open position with pusher **14**. Depending on the particular embodiment of suture clip assembly **3a** used, any sutures placed inside the subject patient are threaded into any of a variety of apertures in suture clip assembly **3a** before suture clip assembly **3a** descends down working channel **15**.

compressed against the plication with minimal or no slack in the suture as shown in FIG. 4. This ensures the suture will properly maintain the plication in the desired bound state.

Referring to FIG. 2, another embodiment of device 1 is shown attached to a distal end of a catheter 20. The procedure described above with respect to an endoscope also applies to a catheter-based version of device 1 except that in this embodiment, pusher 14 is preferably run through a central lumen of catheter 20.

Referring to FIGS. 6-16, a variety of suture clip embodiments are shown that employ a friction fit means to secure one or more sutures. As shown in FIGS. 6, 7 and 10, a suture clip assembly 25 is shown comprised of a suture disk 27 and a disk post 29. In this embodiment, suture disk 27 has portions defining a central disk aperture 30 that is preferably located in the radial center of suture disk 27. Suture apertures 32 are formed in suture disk 27 radially outwardly from disk aperture 30. Suture apertures 32 are adapted to receive sutures 7. One or more suture apertures 32 can be formed in suture disk 27.

Disk post 29 has a disk post main body 34 that is preferably circular with a diameter that matches the diameter of suture disk 27. A locking post 36 extends axially from a face of disk post 29 and is preferably an integral part of disk post 29. Locking post 36 has a cross-sectional diameter that is sized to fit tightly within disk aperture 30. A post aperture 38 runs axially through disk post 29 and locking post 36. Post aperture 38 is adapted to receive sutures 7 and is preferably located in the radial center of disk post 29.

In the embodiment shown in FIG. 6, locking post 36 has a smooth outer surface. As shown in FIG. 8, locking post 36 has a corrugated surface that can also be formed with threading to enhance grasping of sutures 7 when suture clip assembly 25 is manipulated into a closed position. As shown in FIG. 8a, locking post 36 and disk aperture 30 can be formed with matching tapers that allow for one-way insertion of locking post 36 into disk aperture 30 to further enhance grasping of sutures 7.

To use this embodiment of suture clip assembly 25, a suture 7 (extending out of the mouth of the patient in an endoscopic procedure), is thread through post aperture 38 from a distal end of disk post 34 to a proximal face of disk post main body 34. Suture 7 is then fed through suture aperture 32 from a distal face of suture disk

27 to a proximal face of suture disk 27. Both suture disk 27 and disk post 29 are slid along suture 7 until in place in holding chamber 4 of device 1.

Before securing suture disk 27 to disk post 29, any slack in suture 7 is taken up by pulling suture 7 in a proximal direction. To engage disk post 29 to suture disk 27, Force is applied to pusher 14 which forces locking post 36 into disk central aperture 30. Suture 7 becomes entrapped or captured between the mating surface of locking post 36 and disk central aperture 30 as well as between the proximal face of suture disk 27 and the distal face of disk post 29. The tortuous path followed by suture 7 adds to the friction achieved between suture 7 and suture clip assembly 25. FIGS. 11-16 show the path followed by one suture 7 and dual sutures 7 in this embodiment.

Once suture clip assembly 25 has been assembled, suture 7 is captured with suture clip assembly 25 interfacing with plication 5. Suture 7 passes between proximal tang 13 and pusher distal end 19 such that when distal end 19 is forced against proximal tang 13, suture 7 captured. An edge 23 formed in device 1 acts as a knife to sever suture 7 when suture 7 is tensioned by pulling suture 7 proximally while pusher 14 is forced distally through device 1.

In an alternative embodiment shown in FIG. 9, suture disk 27 is not formed with suture apertures 32. Instead, disk post main body 34 is provided with disk post suture apertures 40 that are formed radially outwardly from locking post 36. Sutures 7 are fed through central aperture 30 and through disk post suture apertures 40. Joining of suture disk 27 and disk post 29 results in the same capture of sutures 7 as previously described.

A further embodiment is shown in FIG. 17. In this embodiment, top plate 40 conforms to the shape of a "T" with a flange 62 situated at a bottom portion of top plate 40. Bottom plate 42, separate from top plate 40, is sized and shaped to conform to the shape of flange 62 and has a radially inwardly extending lip 64 dimensioned to conform to the shape of a main trunk 66 of top plate 40. When combined and locked together, the interfacing surfaces of top plate 40 and bottom plate 42 capture suture 7 as shown.

FIGS. 18 - 34 show suture clip embodiments with alignable finger systems that capture suture 7 when placed in an unaligned condition. FIGS. 18 and 19 show a suture clip 3 that is generally rectangular in shape and is comprised of rails 110 that form the perimeter of the clip. A middle rail 112 attached to two rails 110 has a central

humped portion **114** that projects upwardly from the plane occupied by suture clip **3**. Suture apertures **116** one each in middle rail **112** through humped portion **114** and in the two rails **110** oriented in parallel to middle rail **112** are provided through the sides of rails **110** and middle rail **112**. Suture apertures **116** are preferably formed along a plane perpendicular to middle rail **112**.

The offset nature of suture apertures **116** provide sufficient friction to capture sutures **7**. To move suture clip **3** along sutures **7**, pressure is exerted on the bottoms of parallel rails **110** and on the top of hump portion **114** until suture apertures **116** are in alignment. Middle rail **112** must be made of a material that has enough elasticity to flex into coplanar alignment with rails **110** as well as have enough material memory to rebound back into an unaligned state to provide the necessary friction to capture sutures **7**.

FIG. 20 shows an embodiment with suture apertures **116** in rails **110** extending from a top surface to a bottom surface of rails **110**. This configuration provides additional friction by threading sutures **7** through suture apertures **116** from the bottom surfaces of rails **110**. FIG. 21 shows an embodiment which utilizes rails **110** having circular cross-sectional shapes. FIG. 22 shows how forces have to be applied to the individual rails as illustrated by the arrows provided therein. FIG. 23 shows rails **110** and middle rail **112** in alignment such that friction on sutures **7** can be relieved for advancement of suture clip **3** over sutures **7**.

FIG. 24 shows a suture clip **3** with unaligned rails **110** and middle rail **112** situated in an outer tube **120**. Use of an outer tube that has high internal hoop stress and minimal tendencies to set at body temperature is preferred. Braided construction or spring reinforced versions are other alternatives that can be used. Capture of sutures **7** in this embodiment is only possible when outer tube **120** is preferably circular in cross-sectional shape and deformed by a compressive force applied perpendicular to the axis of sutures **7**. Deformation can be achieved by use of a pinching tool passed over sutures **7** and outer tube **120** at the point where sutures **7** is threaded through suture clip **3**.

FIGS. 25 and 26 show a suture clip **3** with rails **110** and middle rail **112** with hexagonal cross-sectional shapes to increase the friction or lockup in the relaxed position, i.e., unaligned position. FIG. 27 shows the same suture clip **3** in an aligned position. FIG. 26 shows a suture clip **3** with rails **110** and middle rail **112** with

radiused cone-shape cross-sections with the radiused portions alternately inverted to again increase lockup in the relaxed position. FIG. 28 shows the same embodiment with the cone-shaped rails in an aligned position.

FIGS. 29 through 32 show a number of embodiments with alternative geometric cross-sectional shapes for the guide rails and the outer tube 120. With these configurations, a snare device could be used by advancing the snare along suture 7 to the point of contact with suture clip 3 where the snare could be used to apply pressure to release the lock on suture 7. Such a device is shown in FIGS. 35-38 referenced below.

FIG. 33 shows the application of a compressive force (designated by the arrows) that causes rails to align which, in turn, releases the friction on suture 7. FIG. 34 shows the same embodiment as FIG. 33 with the compressive force removed which allows the rails to misalign and capture suture 7.

FIG. 35 shows a suture delivery device for suture locks having alignable fingers. An elongate delivery tube 130 is provided with an inner partial tube 132 is fixed to delivery tube 130 proximal to a distal end of delivery tube 130. Inner partial tube 132 has an open distal end and a proximal end that preferably conforms to the shape of an ellipsis. The elliptical shape is designed to cradle a suture lock 3 that incorporates the alignable finger technology described above. An inner tube aperture 134 is formed in the proximal end of, or if elliptically shaped in a proximal apex of, inner partial tube 132.

A snare 136 is provided of which a distal end is attached to an inner wall of delivery tube 130 at the distal end of delivery tube 130. A proximal end of snare 136 is fed through inner tube aperture 134 and extends back to a proximal end of delivery tube 130 where snare 136 can be manipulated by the user.

To operate delivery tube 130, snare 136 is maintained in a loose state so that a suture clip 3 (to which suture 7 has been threaded through) can be mounted into delivery tube 130 and placed against partial inner tube 132. Tension is applied to snare 136 to secure suture clip 3 to delivery tube 130. The force applied to suture clip 3 by tensioning snare 136 causes the rails of the suture clip to align and allow for the suture clip to move along the length of suture 7.

To place suture clip 3 in position in close proximity to and preferably against a sutured tissue fold, delivery tube 130 is advanced to the tissue fold by sliding delivery

tube **130** and suture clip **3** over suture **7**. Once the desired position is reached, tension on snare **136** is released which allows the rails of suture clip **3** to return to an unaligned orientation which causes capture of suture **7**. Preferably, the force generated by the repositioning of the rails causes suture clip **3** to move at least partially out of delivery tube **130**. Once suture clip is in the desired location, delivery tube **130** is retracted and suture **7** severed at a point proximal to suture clip **3**. In one embodiment, delivery tube **130** is provided with an edge that severs suture **7** when delivery tube **130** is retracted.

FIGS. 39-102 show other general embodiments of the suture clip that incorporate cylinders in a variety of configurations to achieve suture capture. FIG. 39-43 show a suture clip embodiment that combines a cylinder with a locking cap. As shown in FIGS. 39-41, a suture lock **3** is shown that comprises an elongate hollow cylinder **140** and a cylinder cap **142**. Cap **142** and an annular slot **144** that is adapted to receive an end of cylinder **140**. A wall slot **146** is provided in a side wall of cap **142** and extends from the exterior surface of the side wall to annular slot **144**.

With this suture clip embodiment, cylinder **140** is advanced over suture **7**. Cap **142** is then slipped over an end of cylinder **140** with suture **7** situated in wall slot **146** as shown in FIG. 40. As shown in FIG. 41, suture **7** is captured by the interfacing surfaces of cylinder **140** and cap **142**. FIGS. 42 and 43 show the tortuous path of suture **7** within suture clip **3** that aids in the capture of suture **7**.

FIGS. 44 and 45 show a suture clip **3** in a cylinder/cap embodiment premounted in device **1**. To effectuate closure of cylinder **140** to cap **142**, a closed end of cap **142** interfaces with distal tang **12**. Cylinder **140** is forced into cap **142** by pusher **14** (not shown) via pusher head **19**.

FIGS. 46-49 show a suture clip **3** in a cylinder/locking rod embodiment. FIG. 46 shows a cylinder **140** being combined with a rod **150**. Rod **150** can be sized to engage the inner wall of cylinder **140** to create a friction fit or can be provided with an optional rod locking flange **152** that is sized to engage either the inner wall of cylinder **140** or an annular cylinder locking channel **154**. Optionally, cylinder apertures **156** are provided, preferably at two locations, along the length of cylinder **140**. Suture **7** can be advanced through cylinder **140** through the ends of the cylinder, through the cylinder apertures **156** or through a combination of the cylinder ends and apertures.

With suture **7** threaded in cylinder **140**, rod **150** is inserted into cylinder **140** such that the interfacing surfaces of rod **140** and cylinder **150** capture suture **7** as shown in FIG. 47. The capture point can include the interfacing surfaces of locking flange **152** and locking channel **154**.

FIGS. 48 and 49 show an alternative embodiment in which a cylinder slot **158** is formed in the sidewall of cylinder **140**. Preferably, slot **158** extends from, and opens onto, an end of cylinder **140**. In this embodiment, suture **7** is threaded through cylinder slot **158** and out the opposite end of cylinder **140**. Again, the interfacing surfaces of cylinder **140** and rod **150** capture suture **7** as shown in FIG. 49.

FIGS. 50 and 51 show a further alternative embodiment in which cylinder **140** is provided with an eyelet **160** that is essentially an elongated section of the sidewall of cylinder **140** that has been separated from the sidewall along the axial length of cylinder **140** and folded either inwardly to form two triangular slots. Suture **7** is threaded through a first end of cylinder **140** and over the exterior surface of eyelet **160** and out the second end of cylinder **140**. Rod **150** is inserted into cylinder **140** which forces eyelet **160** to be reamed outwardly such that suture **7** is captured by the interfacing surfaces of the sidewall of cylinder **140** and the edges of eyelet **160**. The friction created by the addition of eyelet **160** adds to the friction provided by the interfacing surfaces of cylinder **140** and rod **150**.

FIGS. 52-57 show a suture clip **3** employing a dual cylinder system. FIG. 53 shows a cylinder **140** and an inner cylinder **170** that has an outer diameter that is preferably sized to provide a friction fit with the inner wall of cylinder **140**. Inner cylinder **170** has an inner cylinder slot **172** extending from, and opening onto a proximal end of inner cylinder **170**. Cylinder **140** can optionally have a groove **176** formed on a proximal end of cylinder **140** that is used to engage suture **7** as described below.

To operate this embodiment, inner cylinder **170** is advanced over suture **7** (or suture **7** is threaded through inner cylinder **170**) so that suture **7** exits via inner cylinder slot **172** and over the side wall of cylinder **140**. Pull strings **174** are attached to the proximal end of inner cylinder **170** and are threaded through cylinder **140**. To join the cylinders, the user pulls on pull strings **174** toward the proximal end of the endoscope or catheter used to deliver suture clip **3**. Cylinder **140** is maintained in a static position with the proximal portion of chamber **4** of device **1** within which suture

clip 3 in this embodiment can be premounted. The interfacing surfaces of cylinder 140 and inner cylinder 170 capture suture 7 along the portion of the sidewall of inner cylinder 170 that is distal to the distal end of inner cylinder slot 172 as well as the tortuous path followed by suture 7. Suture 7 can be additionally captured by groove 176 such that any pulling of suture 7 will tighten the contact between cylinder 140 and inner cylinder 170. FIG. 53 shows suture clip 3 in a locked position and FIG. 54 shows suture clip 3 set on suture 7 against tissue 5.

FIGS. 55-57 show a modification of the dual cylinder embodiment. In this embodiment, cylinder apertures 178 are formed in the side wall of cylinder 140. Preferably, two coplanar pairs of diametrically opposed cylinder apertures 178 are provided. Inner cylinder 170 is tapered with the taper increasing from the distal end to the proximal end. An inner cylinder aperture 180 is formed in the side wall of inner cylinder 170. Suture 7 can be threaded through any combination of a distal end of cylinder 140, cylinder apertures 178 and a proximal end of cylinder 140 as shown in FIG. 55. Suture 7 is then treaded through the distal end of inner cylinder 170 and out through inner cylinder aperture 180. Suture 7 is then threaded through a pusher aperture 14a formed in pusher 14. Pusher aperture 14a preferably extends to the proximal end of pusher 14.

To join the cylinders together, in one embodiment, cylinder 140 is set against tangs 12 of device 1. Inner cylinder 170 is situated in the proximal end of chamber 4 and is forced into cylinder 140 with pusher 14. The interfacing surfaces of cylinder 140 and inner cylinder 170 capture suture 7 and are aided by the tortuous path followed by suture 7 within this embodiment of suture clip 3. The interfacing surfaces of pusher 14 and suture clip 3 can be used to sever suture 7 distally of suture clip 3.

FIGS. 58 and 59 show a simpler version of suture clip 3 that includes cylinder 140 with cylinder apertures 178. Suture 7 is advanced through a first cylinder aperture then to a second cylinder aperture that is diametrically opposed to the first cylinder aperture then to a third cylinder aperture that is substantially coplanar with the second cylinder aperture and finally through a fourth aperture that is diametrically opposed to the third aperture. Tension is then applied to suture 7 that creates friction between suture 7 and cylinder 140.

An alternative embodiment involving cylinder 140 and a second cylinder 182 that is aligned perpendicular to the longitudinal axis of cylinder 140. Suture 7 is

threaded through cylinder **140**, through a distal end of cylinder **182** and through a second cylinder aperture **184** formed in a sidewall of second cylinder **182**. Tension placed on suture **7** causes friction between the interfacing surfaces of suture **7**, cylinder **140** and second cylinder **182**. Preferably, the distal end of second cylinder **182** contacts the sidewall of cylinder **140**.

FIGS. 60-62 show an alternative embodiment of the dual cylinder embodiment in which second cylinder **182** has a locking jaw **186**. Jaws **186** have a top tang **188** and a bottom tang **190** that are offset with top tang **188** offset distally relative to bottom tang **190**. An optional groove **192** is formed on an uppermost tip of bottom tang **190** that is adapted to receive suture **7**. Second cylinder **182** is preferably made of a material that allows for jaw **186** to be flexed from a closed position (as shown in FIG. 62) to an open position (as shown in FIG. 63) and back to a closed or semi-closed position.

A slot **194** is formed in the sidewall of cylinder **140** that is sized and adapted to receive top tang **188** in locking engagement. Suture **7** is threaded through cylinder **140**, through groove **192** and through second cylinder **182** proximally to and through any device used to place suture clip **3**.

To engage cylinder **140** to second cylinder **182**, cylinder **140** is placed against tangs **12** of device **1**. Second cylinder **182** is positioned in the distal region of chamber **4**. Second cylinder **182** is pushed toward cylinder **140** until top tang **188** contacts cylinder **140** and flexes upwardly and over the exterior of cylinder **140**. Second cylinder **182** is advanced until top tang **188** engages a distal shoulder **196** of aperture **194**. Suture **7** is captured by the interfacing surfaces of top tang **188** and bottom tang **190** as shown in FIG. 62.

FIGS. 64 and 65 show a three tab embodiment of suture clip **3**. In this embodiment, suture clip **3** has two lateral tabs **200** and a central tab **202**. Central tab **202** has a tab flange **204** that preferably extends perpendicular to the longitudinal axis of central tab **202** and is an integral lateral extension of a bottom face of central tab **202**. Tab flange **204** extends from both lateral sides of central tab **202** beyond the adjacent sides of lateral tabs **200**. Suture clip **3** is preferably made of a material that allows for central tab **202** to flex upwardly past the plane occupied by lateral tabs **200** and downwardly past the same plane.

To use this embodiment of suture clip **3**, thread **7** is advanced over lateral tabs **200** and under central tab **202** that is flexed upwardly as shown in FIG. 64. Central tab **202** is then flexed downwardly beyond the plane occupied by lateral tabs **200** so that tab flange **204** contacts the bottom surfaces of lateral flanges **200**. Suture **7** becomes captured by the friction created by the tortuous path followed through the tabs of suture clip **3**.

FIGS. 66 - 68 show another embodiment using cylinder **140** and a hollow rod **210**. In this embodiment, a flap **206** is formed in the sidewall of cylinder **140** by skiving the sidewall. Flap **206** has a flap aperture **208** formed therein. A distal end of flap **206** is bent downwardly so that it occupies part of the lumen of cylinder **140**. Suture **7** is threaded through a distal end of cylinder **140** and through flap aperture **208** from a top side of flap **206** and out through a proximal end of cylinder **140**. Suture **7** is then advanced through a rod lumen **212** of a hollow rod **210** that has an outer diameter that is sized to provide a friction fit with the inner wall of cylinder **140**. Hollow rod **210** is advanced through cylinder **140** within which hollow rod **210** contacts a bottom proximal end of flap **206**. Further advancement of hollow rod **210** forces flap **206** upwardly which captures suture **7** between flap **206** and the sidewall of cylinder **140** as shown in FIG. 68.

FIGS. 69-73 show a variety of embodiments of the wedge principle. FIGS. 69, 70 and 730 show wedge **310** conformed to the shape of a sphere. A wedge string **318** is attached to wedge **310** and is used to apply tension to force wedge **310** into a pliable version of cylinder **140**. Preferably cylinder **140** is made of a material such as plastic that can be deformed to receive wedge **310** that has a diameter that is preferably greater than the diameter of the lumen of cylinder **100**. The introduction of wedge **310** into cylinder **140** captures a present suture **7** between the interfacing surfaces of cylinder **140** and wedge **310**.

FIGS. 71 and 72 show alternative embodiments of wedge **310** combined with cylinder **140**. FIG. 71 shows wedge **310** being solid with a tapered sidewall. FIG. 72 shows wedge **310** with a bulbous proximal end and a domed cap distal end that has a diameter that is preferably greater than the inner diameter of cylinder **140**. Again, suture **7** is captured by the mating surfaces of the components.

FIGS. 74 and 75 show a further embodiment of suture clip **3** comprised of wedge **312** and cone **320**. Wedge **312** has central aperture **314** and cone **320** has a

cone aperture **326** that is formed in the sidewall of cone **320**. Cone **320** can be formed with a pointed or flat tip **322**. In this embodiment, suture **7** is advanced through central wedge aperture **314**, into a cone cavity **324** formed in cone **320** and out through cone aperture **326**. Wedge **310** is then advanced into cavity **324** of cone **320**, the interfacing surfaces of which capture suture **7**. The further wedge **320** is advanced into cone **320** the greater the capture force on suture **7**.

FIGS. 76-83 show additional embodiments of suture clip **3** using various shaped wedges. FIGS. 76 and 77 show cylinder **140** with a tapered wedge **310**. Again, the interfacing surfaces of cylinder **140** and wedge **310** capturing suture **7** as shown in FIG. 77. FIGS. 78, 81, 82 and 83, show a similar embodiment however with cylinder **140** having a cylinder slot **141** formed on the sidewall and extending from, and opening on, an end of cylinder **140**. As described for previous similar embodiments, suture **7** is placed in slot **141** before engagement of cylinder **140** and wedge **310**.

FIGS. 79 and 80 show a yet further embodiment of suture clip **3** in which wedge **310** has a cylindrically shaped main body **313** and a domed and flanged distal end **315**. Suture **7** is captured by the interfacing surfaces of distal end **315** and the inner wall of cylinder **140**.

FIG. 84 shows device **1** with a suture clip **3** loaded into chamber **4**. Cylinder **140** is shown being confined by distal tangs **12** while pusher **14** advances wedge **312** through the lumen of cylinder **140**. An annular cylinder channel **143** is formed on the inner wall of cylinder **140** to receive in mating engagement, an annular flange **317** formed on a proximal end of wedge **312**. Suture **7** enters cylinder **140** via cylinder slot **141** and out the proximal end of cylinder **140**. The interfacing surfaces of cylinder **140** and wedge **312** capture suture **7**.

A final category of suture clip embodiments is shown in FIGS. 85 through 102 that involve a cylinder or rod being wrapped with suture **7** and captured with external semicircular sleeves. FIGS. 85-89 show a rod **400** and a sleeve **410** that is preferably semicircular and more preferably has a hyper semi-circular cross sectional shape that is sized to releasably lock onto rod **400**. Sleeve **410** has sleeve apertures **412** that are preferably formed proximal to distal and proximal ends of sleeve **410**. Suture **7** is threaded through a distal member of the sleeve apertures **412** then wound around rod **400** then threaded through a proximal member of the sleeve apertures **412**. Sleeve

410 is then clipped onto rod **400** as shown in FIGS. 86 and 87. FIGS. 88, 89 and 91-95 show an embodiment in which rod **400** and sleeve **410** are joined at a proximal end. In this embodiment suture clip **3** is made of a material that allows sleeve **410** to be flexed from an open position to a closed position.

FIGS. 90 and 91 show a modification of device **1** that can be used to lock suture clip that incorporates a rod and mating sleeve. As shown, rod **400** and sleeve **420** are mounted in chamber **4**. Pusher **14f** has a distally extending tapered segment **14e** that when advanced distally, forces sleeve **410** to rotate toward rod **400** until sleeve **410** is locked onto rod **400**. A tapered proximal tang **13a** provided proximally to distal tang **12** is situated to contact segment **14e**. Full distal advancement of segment **14e** results in segment **14e** riding along tang **13e** that, in turn, causes the outward flexion of finger **9** which releases suture clip **3**.

FIGS. 96-100 show suture clip **3** in various stages of advancement from a pre-locked position (FIG. 96) to an intermediate position (FIG. 97 and 98) to a locked position (FIGS. 99-100) adjacent to tissue **5**. The process begins by advancing rod **400** down suture **7** toward tissue **5** with a pusher (not shown). Once rod **400** reaches tissue **5**, tension is applied to suture **7**. Sleeve **410** is then advanced distally along suture **7** with a pusher (not shown) until reaching rod **400**. Alternatively, rod **400** and sleeve **410** can be advanced simultaneously by providing sleeve **410** with a suture contacting surface that has additional friction. Any slack in suture **7** is captured between rod **400** and sleeve **410** when locked together. The suture **7** is then severed by the pusher at a point proximal to the suture clip **3**. The suture capturing effect can be enhanced by winding suture **7** about rod **400** before locking sleeve **410** to rod **400**. In alternate embodiments, the mating surfaces of rod **400** and sleeve **410** can be textured or provided with mating projections and cavities to enhance the frictional grasp of suture **7**. It should be noted that a suture tag **7a** can be used to anchor a distal end of suture **7**.

FIGS. 101 and 102 show an additional embodiment of suture clip **3**. FIG. 102 shows rod **400** about which suture **7** is wound. Clamping jaws **500** are closed to capture suture **7** between the interfacing surfaces of rod **400** and clamping jaws **500**. One method that can be used to close clamping jaws **500** employs device **1** with the modifications shown for the rod/sleeve suture clip embodiment. The open end of

clamping jaws **500** are positioned in the distal end of chamber **4** against distal tangs **12**.

FIGS. 132 – 150 illustrate suture clips having either expandable plugs or expandable rings combined with a rigid counterpart ring or plug, respectively. FIGS. 132 - 134 show a suture clip **3** comprising a ring **562** and a mesh plug **560**. Ring **562** is made from a relatively rigid material such as polypropylene to withstand expanding forces generated by plug **560**. Plug **560** is preferably made from an expandable material such as nitinol or an elastomeric material into the mesh pattern shown in FIG. 134. Plug **562** is configured so that the nitinol mesh has a relaxed state that has an outer diameter that exceeds the inner diameter of ring **562**. Suture **7** is captured between an inner wall of ring **562** and an outer surface of plug **560** via the radial outward force generated by ever expanding nitinol based plug **562**.

FIGS. 135 – 141 show the delivery of mesh plug **562** into ring **560**. The process begins by preloading ring **560** into a suture clip delivery device **502**. Resilient collet fingers **504** formed at a distal end of delivery device **502**, have distal tangs **506** that provide a temporary stop to arrest distal movement of ring **560** prior to cinching with plug **562**. Suture **7** is threaded through ring **560** and through delivery device **502**. A plug delivery catheter **563** dimensioned to slide axially through a central bore in delivery device **502**, is preferably preloaded at a distal end with a plug **562** in a compressed state. Catheter **563** is advanced until in close proximity to a proximal edge of ring **560**. A ring pusher **524** dimensioned to slide axially within catheter **563** is advanced distally through catheter **563** to force ring **562** out of catheter **563** and into ring **560**.

With the distal exit of plug **562** from catheter **563**, the radially restraining force provided by an inner wall of catheter **563** is eliminated thereby allowing plug **562** to expand. Suture **7** is captured and held by the friction generated by plug **562** expanding into an inner wall of ring **562**. As shown in FIGS. 138 and 139, plug **562** is preferably longer than ring **560** so that the ends of plug **562** preferably expand beyond the outside diameter of ring **560** to provide a locking function to prevent relative axial movement of plug **562** to ring **560**. Optionally as shown in FIG. 142, ring **560** can be formed with an anti-migration tab **560a** that extends inwardly from the inner wall of ring **560**. Tab **560a** operates to prevent relative axial movement of plug **562** by engaging one or more web apertures formed in the mesh structure of plug **562**.

FIGS. 143 – 150 show an alternate embodiment of the expandable suture clip component design. In this embodiment, plug **562** is the rigid component and ring **560** is a compressible component. Preferably, plug **562** is formed with diagonal channels **562a** formed on an outer surface while ring **560** is formed as a ribbon dimensioned so that the spacing between adjacent ribbon sections **560b** corresponds with the spacing of the plug channels **562a**. With this embodiment, ring **560** is stressed into an initial open, large diameter state for delivery onto plug **562**. Following the insertion of suture **7** into ring **560**, plug **562** is inserted into ring **560** so that suture **7** is positioned between the outer wall of plug **562** and the inner surfaces of ring **560**. Once positioned, ring **560** is allowed to transition to a smaller diameter relaxed state that causes the migration of the individual ribbon sections **560b** into plug channels **562a**. The tortuous path followed by suture **7** by virtue of the plug channels **562a** coupled with the frictional force generated by the compression of ring **560** results in suture clip **3** being secured against axial displacement relative to suture **7**.

A further embodiment of plug **562** is shown in FIG. 150. In this embodiment, plug **562** is formed with enlarged ends that give plug **562** a "dumbbell" shape. The diametrically enlarged ends provide axial stops for mesh ring **560**.

Referring to FIGS. 121-125, the distal end of a low profile single pusher suture clip delivering and locking catheter designed primarily headless suture clip assemblies is shown generally as **1**. A catheter distal end is comprised primarily of a collet **2** to which the other components of distal end **1** are attached. Collet **2** is essentially a cylinder with two or more collet fingers **4** extending distally from a distal end of collet **2**. Collet fingers **4** are biased in an open position. Extending radially inwardly from a distal end of each collet finger **4** is a collet finger flange **6** that functions as a stop to arrest distal advancement of a suture clip loaded into collet **2**. The combination of the distal end of collet **2**, collet fingers **4** and distal flanges **6** define a collet cage within which the components of a suture clip are releasably encapsulated for delivery to a sutured tissue site. The cage further functions to align the suture clip components for assembly.

In a preferred embodiment, collet finger flanges **6** have radiused outer distal edges **8** to minimize trauma to a patient and radiused inner distal edges **10** to ease loading of suture clip components. In a preferred embodiment, outer distal edges **8** extend radially outwardly beyond outer collet finger walls **14** to function as a stop for

an outer sliding sleeve 30 described below. Inner proximal faces of collet finger flanges 6 are oriented to a longitudinal axis of collet fingers so that a plane occupied by flange proximal surfaces 18 forms an angle from about 90° to about 135° and preferably about 128° to optimally balance the need to provide a stopping function against the need to not hinder suture clip deployment from the delivery catheter. Optionally, collet finger flanges 6 can be formed to extend radially outwardly from the outer wall of collet fingers 4 to act as a distal stop for a sliding sleeve 30.

Finger slots 12 are formed between and defined by collet fingers 4 and function as egress ports for sutures threaded through the components of a suture clip loaded into the collet cage. Because collet fingers 4 are biased in an open position, a radially constraining force need only be applied to move the fingers from an open, suture clip loading/releasing position to a closed, suture clip confining position. Alternatively, finger collets 4 can be biased in a closed position.

The distance between a proximal face of collet finger flanges 6 and the distal end of the body of collet 2 is set to preferably accommodate at least one set of unassembled suture clip components along with two unassembled suture clip plugs 62. This distance can be modified to accommodate different numbers of suture clip plugs.

Situated within a hollow chamber defined by the inner walls of collet 2 is a cylindrically shaped pusher 24. Pusher 24 slides freely within collet 2. Pusher 24 is preferably adapted to matingly engage a proximal end of a suture clip plug situated in the collet cage. Distal advancement of pusher 24 engages the suture clip plug and drives the suture clip plug distally into a suture clip ring. Collet finger flanges 6 function as a stop for the suture clip ring so that the distal axial force applied causes engagement of the suture clip components.

Pusher 24 is formed with diametrically opposed guide tabs 43 that ride axially within diametrically opposed channels formed in the inner walls of collet 2. Extending radially outwardly from guide tabs 43 are depressible finger tabs 45.

Situated in coaxial relationship with and freely sliding about collet 2 is outer sliding sleeve 30 that performs at least two functions; providing radial force against collet fingers 4 to maintain the fingers in a closed position during suture clip delivery to a tissue site to minimize potential trauma that could be caused by open collet fingers and providing a means to sever the tail ends of a suture that has been secured with

a suture clip. When advanced distally, sliding sleeve 30 encompasses collet fingers 4 and restricts radial movement of the fingers regardless whether the fingers are biased in an open or closed position.

When proximally retracted, sliding sleeve 30 severs directly or cooperates with other components to sever suture material proximal to a secured suture clip. In one embodiment, a distal end 35 of suture slot 34 engages the suture and carries it toward a distal end of the body of collet 2. When the distal end of suture slot 34 travels past the distal end of the body of collet 2, the suture is severed. In another embodiment, sliding sleeve 34 interacts with a fixed cutter 42, described below, to sever the suture tail ends. In yet a further embodiment suture slot distal end 35 is sharpened to perform the severing function when sliding sleeve 30 is proximally retracted.

Diametrically opposed sliding sleeve locking slots 47 are formed in the outer cylindrical wall of sliding sleeve 30 in close proximity to a proximal end of sliding sleeve 30. Locking slots 47 are adapted to receive finger tabs 45 of pusher 24. Interlocking of finger tabs 45 and locking slots 47 provide a means to retract sliding sleeve 30 with pusher 24. To retract sliding sleeve 30, pusher 24 is proximally retracted until it contacts a proximal end 31 of sliding sleeve 30. Upon contact finger tabs 45 engage locking slots 47 which allows proximal retraction of sliding sleeve 30 via proximal retraction of pusher 24. To advance sliding sleeve 30, finger tabs 45 have to be manually depressed out of the patient. Sliding sleeve 30 can then be manually advanced to contain collet fingers 4 in a closed position.

In an alternate embodiment as shown in FIGS. 132 and 133, a pusher head 24a extends from a distal end of pusher 24. Pusher head 24a has portions defining an axially oriented sleeve pin slot 24b that is adapted to receive in sliding engagement, a sliding sleeve pin 40a. Sliding sleeve pin 40a extends radially inwardly from sliding sleeve 30 and is dimensioned to freely slide axially within sleeve pin slot 24b. Sleeve pin slot 24b is positioned within pusher head 24a so that the pusher 24/pusher head 24a assembly can be advanced distally sufficient to completely cinch the suture clip assembly without advancing sliding sleeve 34 past the distal end of collet fingers 4. With this arrangement, a proximal end of sleeve pin slot 24b acts as a stop for sliding sleeve 30 and thereby eliminates the need for collet finger flanges 6 to provide a distal stop for sliding sleeve 30. A distal end of sleeve pin slot 24b is positioned so that retraction of the pusher 24/pusher head 24a assembly

causes the distal end of sleeve pin slot **24b** to engage sliding sleeve pin **40a** and retract sliding sleeve **30** a sufficient axial distance to allow release of the cinched suture clip assembly. A subsequent forward advancement of the pusher **24**/pusher head **24a** assembly causes the proximal end of sleeve pin slot **40b** to engage sliding sleeve pin **40a** that translates the distal motion of pusher **24** into a distal motion of sliding sleeve **34** to retract collet fingers **4** radially inwardly for full retraction of delivery device **1** out of the patient.

At least one suture slot **34** is formed toward a distal end **32** of sliding sleeve **30** to provide egress for excess suture material that typically extends beyond the orifice through which the catheter is inserted. It is important that finger slots **12** and suture slots **34** are at least partially aligned to allow a path for excess suture material to exit the suture clip delivery device. To accomplish alignment with embodiments lacking sliding sleeve pin **40a**, suture slot **34** functions as an alignment slot to receive an alignment pin. An alignment pin **40** is affixed to collet **2** and dimensioned to freely slide within alignment suture slot **34**. The length of alignment slot **34** limits the proximal and distal travel of sliding sleeve **30**. Alignment pin **40** is positioned on collet **2** at a point proximal to the distal edge and through a fixed cutter **44**, if present. Suture slot **34** is positioned in sliding sleeve **30** such that at least one finger slot **12** and suture slot **34** are at least partially aligned along their longitudinal and radial axes. Preferably two diametrically opposed sets of finger slots **12** and suture slots **34** are provided to allow egress for each end of a suture. Only one alignment pin **40** need be provided to accomplish radial alignment.

An optional feature of the presently described embodiment is a fixed cutter **42**. Cutter **42** is preferably a metallic ring formed about and affixed to collet **2** that has a distal edge **44** that is sufficiently sharp to sever suture material. The ring is used for embodiments that are preferably injection molded. However, filled or engineered plastics can be used to obviate the need for fixed cutter **42**.

For the single pusher embodiment, a conventional control handle (not shown) with a single pusher knob attached directly to the collect cage is used to advance and retract pusher **24**. The control handle does not form a part of the invention.

To load suture clip components in the single pusher embodiment, pusher **24** is fully retracted so that sliding sleeve **30** is engaged and proximally retracted to remove the radial constraint of collet fingers **4** which expand into an open position.

With collet fingers **4** arranged in an open position, two stackable suture clip plugs can be placed in the collet cage. Next, the ends of a suture **80** that has been used to stitch tissue in the internal regions of an individual are threaded through a suture clip ring and into thread apertures formed in a suture clip plug. The suture ends are then fed through either the same or separate sets of finger slots **12** and suture slots **34** so that the ends of the suture are arranged external to the suture clip delivery catheter. The suture clip plug **62** is then placed in a proximal end of the collet cage distal to the first two suture clip plugs **62** and the suture clip ring **60** is placed in a distal end of the collet cage where the ring preferably engages at least one of the collet ring flanges **6** to prohibit distal travel of the ring. It is to be understood that the collet cage can be sized to accommodate a plurality of suture clip plugs that can be stacked for deployment into suture clip rings that must be loaded one per suture clipping procedure.

With the suture clip components loaded, pusher **24** engaged to sliding sleeve **30** via the engagement of finger tabs **45** and locking slots **47** is distally advanced until sliding sleeve **30** reaches its maximum distal advancement point. At this point, due to the length of pusher **24**, pusher **24** cannot engage the next suture clip plug **62** until finger tabs **45** are depressed to release sliding sleeve **30** that enables the operator to distally reposition pusher **24**. Sliding sleeve **24** is sized so that locked engagement with sliding sleeve **30** prevents the distal end of pusher **24** from coming into contact with the next suture clip plug without being disengaged from sliding sleeve **30**. This configuration effectively captivates the suture clip components for delivery to the sutured tissue site.

To operate the single pusher embodiment, the control knob attached to pusher **24** is distally advanced. This causes a distal end of pusher **24** to engage the most proximal suture clip plug **62**. The axial force generated is transferred through the two most proximal suture clip plugs **62** to the third most distal suture clip plug **62** that, in turn, engages suture clip plug **60** so that a complete suture clip is formed and cinched in close proximity to the stitched tissue. Once pusher **24** is maximally advanced to a bottom out position, the control knob is proximally retracted to engage sliding sleeve **30** as described above. Proximal retraction of sliding sleeve **30** severs the ends of suture **80** at a point proximal to the assembled suture clip via the interaction of the distal end of suture slot **34** and either the distal edge **44** of cutter **42** or the distal edge

of the body of collet 2. To remove the catheter from the patient, pusher 24 is again proximally advanced. Due to the one-way interaction of finger tabs 45 and locking slots 47, distal advancement of pusher 24 causes sliding sleeve 30 to be advanced to again radially constrain collet fingers 4. Pusher 24 is distally advanced until sliding sleeve 30 reaches maximum advancement. At this point the catheter can be safely removed from the patient.

To begin another cycle, a suture clip ring is loaded into the collet cage. In one embodiment, a ring loading rod or mandrel (not shown) is used to load rings 60 into the distal end of the collect cage. The rod has a diameter that is sufficiently less than the inside diameter of the rings 60 to allow the free movement of rings 60 from the rod into the open collet cage. To insert a ring, the rod is forced into the radiused finger collet flanges 6 until it stops. The entering ring 60 has a diameter that is greater than the inner diameter of the finger collet flanges 6 that causes the flanges to flex inwardly. When the ring 60 is advanced proximally past the proximal faces 18 of flanges 6, the flanges flex back into their initial position and captivate the ring. The rod is then removed. To prepare for another suture clip assembling and cinching cycle, sliding sleeve 30 is released from pusher 24 and distally advanced to radially constrain collet fingers 4.

In another embodiment shown in FIG. 126, a dedicated finger hold 76 is employed to advance and retract sliding sleeve 30. In this embodiment, a collect finger hold 74 situated at a proximal end of the collet cage provides a finger grasping point to effectuate relative movement of pusher 24 and sliding sleeve 30. A thumb ring 72 is provided at a proximal end of pusher 24. To advance pusher 24, finger hold 74 is grasped while thumb ring 72 is advanced relative to finger hold 74. This enables pusher 24 to engage a suture clip plug to commence engagement of the plug with a suture clip ring. Once pusher 24 has bottomed out (a condition that can be preset by the length of pusher 24 relative to collet 2) the suture clip is fully assembled with a captured suture.

To deploy the suture clip and sever the suture ends, a sliding sleeve finger hold 76 is grasped and retracted while maintaining hold of thumb ring 72. This severs the excess suture material. If the collet fingers are pre-biased in an open position, the collet fingers will spring open absent the radially constraining force of sliding sleeve 30. If finger collets 4 are pre-biased on the closed position, a modification to collet 2

and pusher 24 has to be employed. A ramp 16 is formed on an inside wall of collet 2 at a point proximal to the area where the suture clip components are placed in the collet cage. Ramp 16 tapers radially inwardly from a distal to a proximal end. A pusher taper 17 is provided proximal to the distal end of pusher 24 and adapted to engage ramp 16. Proximal retraction of pusher 24 engages ramp 16 that causes collet fingers 4 to open and release the completed suture clip. To begin a new cycle, suture clip components are loaded into the collet cage and pusher 24 is partially advanced to effectuate the disengagement of ramp 16 and pusher 24 which allow collet fingers 4 to return to the pre-biased closed position.

The suture clips used with the suture clip delivery catheter described herein have plugs without heads. In a preferred embodiment as shown in FIGS. 127-129, plug 62 that is preferably injection molded, has a main shaft 68 that is adapted to frictionally engage the inner walls of ring 60. Extending from the distal and proximal ends of plug 62 are a plurality of plug locking tabs 63 which have outer faces that are radiused about the edges to provide ease of advancement into ring 60 which is also preferably injection molded. Locking tabs 63 are formed with sufficient flexibility to distort to ease advancement into ring so that their overall diameter is reduced while traveling through ring 60. Once the distal most locking tabs emerge from the distal end of ring 60, preferably simultaneous with the contact of the proximal locking tabs 63 with the proximal end of ring 60, the distal locking tabs 63 spring back to their original radially expanded state. The diameter of the flanges is set to be greater than the outside diameter of ring 60 so that when fully radially expanded, locking tabs 63 situated on the proximal and distal ends of plug 62 cooperate to positively lock ring 60 in an axial direction as shown in FIG. 130.

To reduce the effort needed to advance suture 80 about plug 60, plug guide slots 67 are formed between the side surfaces of locking tabs 63. A central diverter 65 is formed extending from the central distal end of plug 60. Diverter 65 has tapered sidewalls that increase radially outwardly from a distal to a proximal end. This configuration facilitates tracking and the radial disposition of suture 80 into guide slots 67. In one embodiment, diverter 65 extends distally beyond the distal end of plug 62 and an engaged ring 60 so that when the assembled suture clip is appended to suture 80, diverter 65 contacts the sutured tissue and causes fibrosis which leads to a

thickening of the tissue. It is believed that this enhances the therapeutic effect of the procedure in GERD patients.

To permit stacking of multiple plugs 62, a substantially cylindrical plug cavity 61 is formed on the distal end of plug 60 and a corresponding axially extending cylindrical plug projection 69 is formed in the proximal end. To ensure positive engagement, plug projection 69 is extended above plug locking tabs 63. Plug cavity 61 and plug projection 69 are sized to loosely mate when a plug cavity 61 in the distal end of one plug is aligned with a plug projection 69 of an adjacent plug. The size tolerances for the respective mating components are maintained sufficiently loose not to interfere with suture clip deployment but tight enough to provide axial and radial alignment during the application of compressive forces to join a plug to a ring in the delivering and locking catheter described herein.

In practice, diverter 65 feeds suture 80 into guide slot 67 that is sized to allow the free movement of plug 60 along suture 80. This configuration provides a suture clip plug that decreases the effort needed to advance the plug over the ends of a suture before loading into the suture clip delivering and locking device.

A further suture clip embodiment employs rings and plugs with interlocking ribs or scales. As shown in FIG. 131, ribs 90 are provided circumferentially about the inner wall of ring 60. Corresponding plug ribs 97 are provided about the outer sidewall of plug 62. The ribs are configured to allow for the advancement of the plug into the ring with minimal effort. The ribs are tapered to allow the plug to be inserted into the ring in a distal direction and create an interference that prevents or resists proximal retraction of plug 62 out of ring 60. The suture 80 becomes entrapped between the inter-engaging ribs. The depth of the scale feature as well as the angle or taper is dependent on the suture size, material and degree of locking needed such as the life expectancy of the individual. Significant profiles will provide higher holding forces that can also adversely affect the life expectancy of the captured suture. The hardness of the components also should be factored into the design. The profile selected is preferably easily molded on the plug with the mold pulling off in the correct fashion. The inner ring detail becomes less of a challenge with the use of a spiral rib that allows the mold pin to be unthreaded. Optionally, a proximal stop 94 can be employed to limit distal advancement of the plug absent plug locking tabs 63. In the

embodiment shown in FIG. 131, plug projection 69 and plug cavity 61 are shown having mating convex and concave domed surfaces, respectively.

Referring to FIGS. 134-138, the distal end of a double pusher suture clip delivery and locking catheter is shown generally as 1. Catheter distal end 1 is comprised primarily of a collet cage 2 to which the other components of distal end 1 are attached. Collet cage 2 is essentially a cylinder with two or more collet fingers 4 extending distally from a distal end of collet cage 2. Extending radially inwardly from a distal end of each collet finger 4 is a collet finger flange 6 that functions as a stop to arrest distal advancement of a suture clip loaded into collet cage 2. The combination of the distal end of collet cage 2, collet fingers 4 and distal flanges 6 define a cage within which the components of a suture clip are releasably encapsulated for delivery to a sutured tissue site. The cage further functions to align the suture clip components for assembly.

In a preferred embodiment, collet finger flanges 6 have radiused outer distal edges 8 to minimize trauma to a patient and radiused inner distal edges 10 to ease loading of suture clip components. In a preferred embodiment, outer distal edges 8 extend radially outwardly beyond outer collet finger walls 14 to function as a stop for an outer sliding sleeve 30 described below. Inner proximal faces of collet finger flanges 6 are oriented to a longitudinal axis of collet fingers so that a plane occupied by flange proximal surfaces 18 forms an angle from about 90° to about 135° and preferably either 135° or 90° with 90° being the most preferred to maximize the stopping function.

Finger slots 12 are formed between and defined by collet fingers 4 and function as egress ports for sutures threaded through the components of a suture clip loaded into the collet cage. Preferably, collet fingers 4 are biased in an open position so that radial force need only be applied to move the fingers from an open, suture clip loading/releasing position to a closed, suture clip confining position. Alternatively, finger collets 4 can be biased in a closed position.

Formed on an inner wall and toward the proximal end of collet fingers 4 are ramps 16 that taper radially inwardly from proximal to distal ends. Ramps 16 function as cam surfaces that when engaged with a pusher, as described below, cause collet fingers 4 to open. The distance between a proximal face of collet finger flanges 6 and the most distal point of ramps 16 is set to accommodate at least one set of

unassembled suture clip components. This distance can be modified to receive the components for multiple suture clips.

Situated within a hollow chamber defined by the inner walls of collet cage 2 is an outer pusher 20 that freely slides within collet cage 2. Pusher 20 is preferably a hollow cylinder. A distal end 22 of outer pusher 20 is formed with a taper on the outside wall of pusher 20 that preferably conforms to and mates with the angle formed by ramp 16. Distal advancement of outer pusher 20 engages pusher distal end 22 with ramp 16. As outer pusher 20 slides distally along ramp 16, collet finger 4 is forced open. Outer pusher 20 can be used with either a collet finger that is biased in a closed position or an open position.

Situated within the hollow chamber formed by the walls of outer pusher 20 is cylindrically shaped inner pusher 24. Inner pusher 24 slides freely within outer pusher 20. Inner pusher 24 is designed to engage a head of a suture plug situated in the collet cage. Distal advancement of inner pusher 24 engages the suture plug and drives the suture plug distally into a suture clip ring. Collet finger flanges 6 function as a stop for the suture ring so that the distal axial force applied causes engagement of the suture clip components.

An inner pusher bore 26 is formed in inner pusher 24 and extends from a point proximal to the distal end of inner pusher 24 proximally through and out a proximal end of inner pusher 24. Inner pusher bore 26 provides a chamber for receiving a wire (not shown) that is used to apply axial force to inner pusher 24. Use of a wire provides adequate force to accomplish suture clip assembly and allows for flexibility over the length of the catheter.

Situated in coaxial relationship with and freely sliding about collet cage 2 is outer sliding sleeve 30 that performs at least two functions; providing radial force against collet fingers 4 to maintain the fingers in a closed position during suture clip delivery to a tissue site to minimize potential trauma that could be caused by open collet fingers and providing a means to sever the tail ends of a suture that has been secured with a suture clip. When advanced distally, sliding sleeve 30 encompasses collet fingers 4 and restricts radial movement of the fingers regardless whether the fingers are biased in an open or closed position. In this position, sliding sleeve 30 prevents outer pusher 20 from prematurely opening the collect.

When proximally retracted, sliding sleeve **30** severs directly or cooperates with other components to sever suture material proximal to a cinched suture clip. In one embodiment, a distal end of suture slot **34** engages the suture and carries it toward a distal end of the body of collet cage **2**. When the distal end of suture slot **34** travels past the distal end of the body of collet cage **2**, the suture is severed. In another embodiment, sliding sleeve **34** interacts with a fixed cutter **42**, described below, to sever the suture tail ends.

At least one suture slot **34** is formed toward a distal end **32** of sliding sleeve **30** to provide egress for excess suture material that typically extends beyond the orifice through which the catheter is inserted. It is important that finger slots **12** and suture slots **34** are at least partially aligned to allow a path for excess suture material to exit the suture clip delivery device. To accomplish alignment, an alignment slot **36** is formed preferably near a proximal end of sliding sleeve **30**. An alignment pin **40** is affixed to collet cage **2** and dimensioned to freely slide within alignment slot **36**. The length of alignment slot **36** limits the proximal and distal travel of sliding sleeve **30**. Alignment pin **40** is positioned on collet cage **2** and alignment slot **36** is positioned in sliding sleeve **30** such that at least one finger slot **12** and suture slot **34** are aligned along their longitudinal axes. Preferably two diametrically opposed sets of finger slots **12** and suture slots **34** are provided to allow egress for each end of a suture.

An optional feature of the presently described embodiment is a fixed cutter **42**. Cutter **42** is preferably a metallic ring formed about and affixed to collet **2** that has a distal edge **44** that is sufficiently sharp to sever suture material. The ring is used for embodiments that are preferably injection molded. However, the use of filled or engineered plastics can be used to obviate the need for fixed cutter **42**.

For the double pusher embodiment, a pistol grip control handle, well known in the art, is used to manipulate the various sliding components of the catheter. As shown in FIG. 139, pistol grip control **50** has three control surfaces for advancing and retracting the inner pusher **24**, the outer pusher **20** and the outer sliding sleeve **30**. A first control knob **52** and a second control knob **54** are coaxially arranged at a proximal end of pistol grip **50** and operate inner pusher **24** and outer pusher **20**, respectively. A third control knob **56** extends from a top surface of, and in the distal end of, pistol grip **50**. Third control knob **56** is connected to and operates outer sliding sleeve **30**.

The first control knob **52** is connected to inner pusher **24** via a wire (not shown) that is preferably 0.030 inches in diameter and that fits within and frictionally engages the walls defining inner pusher bore **26**. The second control knob **54** is connected to outer pusher **20** via a first hypotube (not shown) coaxially arranged about the inner pusher wire and that is preferably 0.042 inches in diameter. The pistol grip control **50** is attached to the catheter distal end **1** (the collet cage assembly) by a second hypotube **3** that is preferably 0.050 inches in diameter and coaxially arranged about the first hypotube. The third control knob **54** is attached to sliding sleeve **30** via a third hypotube (not shown) that is preferably about 0.065 inches in diameter and coaxially arranged about the second hypotube. Bushings between the hypotubes are provided in the collet cage assembly to seal the assembly and do not form a part of the invention. Preferably, the outer diameter of the catheter distal end **1** is 0.067 inches when all the components are assembled. This ensures a wide application of use for the invention.

To load suture clip components in the double pusher embodiment, first control knob **52** and third control knob **56** are placed in proximally retracted positions. If collet fingers **4** are biased in an open position, second control knob **54** can also be placed in a proximally retracted position. Otherwise, second control knob **54** is placed in a distally advanced position to open collet fingers **4** by causing distal end **22** of outer pusher **20** to engage ramps **16**.

With collet fingers **4** arranged in an open position, ends of a suture **80** that has been used to stitch tissue in the internal regions of an individual are threaded through a suture clip ring and into thread apertures formed in a suture clip plug. The suture ends are then fed through either the same or separate sets of finger slots **12** and suture slots **34** so that the ends of the suture are arranged external to the suture clip delivery catheter. The suture clip plug is then placed in a proximal end of the collet cage and the suture clip ring is placed in a distal end of the collet cage where the ring preferably engages at least one of the collet finger flanges **6** to prohibit distal travel of the ring. It is to be understood that the collet cage can be sized to accommodate a plurality of suture clip plugs that can be stacked for deployment into suture clip rings that must be loaded one per suture clipping procedure.

As shown in FIGS. 140 and 141, with the suture clip components loaded, second control knob **54** is retracted if previously advanced, and third control knob **56**

is distally advanced so that outer sliding sleeve **30** engages and applies a radially constraining force to collet fingers **4** to maintain the fingers in a closed position during insertion of the catheter into a patient. In this configuration, catheter distal end **1** is advanced to the suture-clipping site in a patient.

To operate the double pusher embodiment, first control knob **52** is distally advanced so that inner pusher **24** engages the suture clip plug and forces a distal shaft of the plug into the suture clip ring. The frictional engagement of the suture clip plug to the suture clip ring captures the suture **80** via frictional engagement as shown in FIG. 142. The advancement of inner pusher **24** also causes the suture clip components to be cinched in close proximity to the stitched tissue. Once the plug has been secured to the ring and the assembled suture clip cinched to the stitched tissue, third control knob **56** is retracted to release the radial force applied to the collet fingers **4** by sliding sleeve **30**. The proximal retraction of sliding sleeve **30** also causes a distal end of suture slot **34** to engage suture **80** and carry it proximally toward either the sharp distal end of the collet cage **2** or the distal edge **44** of fixed cutter **42** as shown in FIG. 143. When the distal end of suture slot **34** passes proximally beyond either the distal end of the collet body or distal edge **44**, the suture is severed proximal to the assembled clip as shown in FIG. 144. The severed ends of the suture can then be pulled out of the individual.

If collet fingers **4** are biased in a closed position, second control knob **54** is distally advanced to ramp open the collet fingers to release the assembled plug as shown in FIG. 145. Once the suture clip has been released as shown in FIG. 146, second control knob **54** is retracted and third control knob **56** is advanced to place collet fingers **4** in a closed position to reduce the potential for trauma when the catheter is removed from the individual.

In an alternate embodiment, outer pusher **20** is eliminated as shown in FIG. 147. Optional fixed cutter **44** is also not present in FIG. 147. In this alternate embodiment, collet cage **2**, outer sliding sleeve **30** and inner pusher **24** are configured the same as with the double pusher embodiment. Ramps **16** formed on the inner walls of the collet fingers can be eliminated. To ramp open the collet fingers, the proximal surfaces of the collet finger flanges **6** are preferably provided with a taper that increases radially inwardly from a proximal to a distal end and that preferably forms an inclusive angle with the body of the associated collet finger of preferably

from about 128° to about 135° to perform the cam function of ramps **16**. Like the double pusher embodiment, sliding sleeve **34** is maintained in a distally advanced position to radially constrain collet fingers **4** while inner pusher **24** is distally advanced to secure the suture clip components and cinch the assembled suture clip to the stitched tissue.

When inner pusher **24** is proximally advanced, a distal edge of the suture clip ring engages the beveled surfaces of collet finger flanges **6** the combination of which generates a ramp opening force against the constrained collet fingers **4**. Proximal retraction of sliding sleeve **30** allows finger collets **4** to return to their pre-biased open positions and severs the ends of the suture in the same manner as with the double pusher embodiment. The ramp opening force generated by inner pusher **24** can aid the opening process and facilitate release of the assembled suture clip. As with the double pusher version, sliding sleeve **30** is again distally advanced to constrain collet fingers **4** for removal of the catheter from the individual. Essentially, elimination of outer pusher **20** reduces the three-step process of the double pusher embodiment to the two-step process of the single pusher embodiment.

Another embodiment of the single pusher system employs ramps **16** with or without the tapered collet finger flanges **6**. In this embodiment, the collet cage assembly is used with a suture clip that is comprised of a ring **60** and a plug **62** having a head **64** with a chamfered edge **66**, as shown in FIG. 148, that engages and mates with ramps **16** to ramp open finger collets **4** when the plug is distally advanced. This configuration is applied particularly with collet fingers that are biased in a closed position.

In a further collet cage assembly embodiment, the need for resilient collet fingers is eliminated as shown in FIGS. 165 – 171. Referring to FIGS. 165, 166, 168 and 172, collet cage **2** has a collet cage body **2a** with axially oriented finger slots **2b** (shown in FIGS. 170 and 171), dimensioned to receive pivot collet fingers **4a**. Formed in a sidewall of collet cage body **2a** are collet pin apertures **4d** (shown in FIGS. 170 and 171), adapted to receive collet finger pin **4c**. Collet pin apertures **4d** are formed on either side of each finger slot **2a** and are aligned in pairs to receive rod-shaped collet finger pin **4c**. Formed in the bodies of pivot collet fingers **4a** are finger apertures **4e** also adapted to receive collet finger pin **4c**. Pin **4c** is secured within collet pin apertures **4d** via friction fit, adhesive or mechanical manipulation of pin **4c** to cause

the cold flow of material at the ends of pin **4c**. The materials used for collet cage body **2a** and collet fingers **4a** described herein provide sufficient lubricity to allow for the free rotation of collet fingers **4a** about pin **4c**.

Pivot collet fingers **4a** have the same distal finger flanges **6** with beveled inner surfaces to provide a temporary axial stop for the suture clip components as described for the resilient collet finger embodiments. Collet fingers **4a** have proximal ends **4f** dimensioned so that shortest distance between two opposing collet fingers **4a** is a dimension *D*. The transition between proximal ends **4f** and the main body of fingers **4a** forms a shoulder **4b** positioned proximal to the point of connection to pin **4c**. In this configuration, collet fingers **4a** acts as dogs that are radially constrained in a position parallel to a central longitudinal axis of collet cage body **2a** via a temporary radial constraint. A radially extended distal end of pusher **24**, plug head **64**, plug **62** in headless embodiments, or other components can act as the source of the radial constraint by virtue of having diameters that are just slightly less than distance *D*.

Restraint is accomplished, as shown in FIG. 165, when the restraining component (plug head **64** in FIG. 165), is positioned to contact collet finger proximal ends **4f** in a pre-cinched condition. Once the restraining component is advanced distally past proximal ends **4f**, as shown in FIG. 167, the suture clip components, i.e., plug **62** and ring **60**, are cinched and collet fingers flanges **6** are free to rotate radially outwardly to release the cinched suture clip. As with other previously described embodiments, the same distal advancement of pusher **24** causes a suture (not shown) to be severed proximal to the suture clip components. With the pivoting collet fingers, sliding sleeve **30** can be eliminated, if desired, because radial restraint is provided internally.

Shown in FIG. 169 is an alternate embodiment of the pivoting collet finger design that eliminates the need for pin **4c** and any potential problems with wall thickness and removal of cross-sectional area inherent when forming finger apertures **4e** in pivot collet fingers **4a**. A pivot ring **30a** is secured to the exterior of collet cage body **2a** at a point along the length of pivot collet fingers **4a**. As with the previously described embodiment, radial constraint is provided by pusher **24**, plug **62** or by some other component when the system is in a pre-cinched condition. Once the constraining component is advanced distally past collet finger proximal ends **4f**, pivot collet fingers **4a** pivot about a distal edge **30b** of pivot ring **30a** such that collet finger

flanges **6** rotate radially outwardly to allow the release of the cinched suture clip components.

In a preferred embodiment of the single pusher system, the entire collet cage **2** is miniaturized to allow for collet cage **2** and the attached hypotubes to fit within the working channel of an endoscope. The miniaturized collet cage **2** and a control handle **90** for the collet cage are shown in FIGS. 157, 163 and 164. Preferably, the outer diameter of collet cage **2** is about 0.094 inches and the length is about 0.42 inches to easily accommodate the space available in the working channel of an endoscope (typically between about 0.110 and 0.115 inches) and more particularly to enable negotiation of the 45° bifurcation that is typically located toward the distal end of an endoscope.

Collet cage **2** is connected to control handle **90** via a collet cage hypotube **3**. Preferably, hypotube **3** is laser welded to collet cage **2**. A proximal end of collet cage hypotube **3** is attached to a collet cage handle bushing **100**. Bushing **100** is used to allow for laser welding of hypotube **3** to a collet cage handle **98**. Collet cage handle **98** performs the function of orienting the axial relationship of collet cage **2** to the two axially moving components, sliding sleeve **30** and pusher rod **94** (pusher **24**). Situated about collet cage hypotube **3** is sliding sleeve hypotube **3a**. A distal end of hypotube **3a** is attached via laser welding to sliding sleeve **30** and a proximal end is attached to a sliding sleeve bushing **104**. This enables hypotube **3a** to be laser welded to a sliding sleeve handle **102**. Sliding sleeve handle **102** is used to control axial movement of sliding sleeve **30** relative to collet cage **2**. To increase the lubricity of the system for ease of delivery through an endoscope, an outer sheath **3b** (preferably made from polyetherblockamide tubing, white (2% TiO₂)) is adhered to sliding sleeve hypotube **3a** with an adhesive such as Tra-Bond® #FDA-2 epoxy.

Provided within collet cage hypotube **3** is pusher rod **94**. As described above, pusher rod **94** (inner rod **24** in other embodiments) is used to cinch plug **62** into ring **60**. A proximal end of pusher rod **94** is secured to an interior bore of a cinch handle insert **96** via pins or screws **107** and helicoils **108** shown in FIG. 164. An exterior surface of cinch handle insert **96** is secured via pins or screws (not shown) to cinch handle **92**.

The preferred materials used to make the various collet cage **2** and control handle **90** components are as follows. Collet cage **2**, sliding cutter sleeve **30**,

alignment pin **40**, inner rod **24**, sliding sleeve bushing **104**, cage handle bushing **100** and cinch handle insert **96** are made from either 304L or 316L stainless steel. Pusher rod **94**, collet cage hypotube **3** and sliding sleeve hypotube **3a** are made from 304 stainless steel. Sliding sleeve handle **102**, collet cage handle **98** and cinch handle **92** are made from Delrin®. To enhance the distinction among the three handles, each can be made from a different color of Delrin®. For example, sliding sleeve handle **102** can be red, collet cage handle **98** can be white and cinch handle **92** can be black.

In an alternate embodiment, control handle **90** can be provided with springs to ensure that the proper orientation of the moving parts is maintained before and after the delivery and cinching of the suture clip components. First return spring **105** provides an axial force that maintains pusher rod **94** in a proximal position while second return spring **106** provides an axial force that maintains sliding cutter sleeve **30** in a distal position. The springs are selected to provide enough tension to maintain the pusher rod and sliding cutter sleeve in starting positions when advancing and retracting the suture clip delivery device. This provides desired protection to an endoscope that could potentially be damaged if collet fingers **4** were allowed to remain in radially extended positions when advancing or retracting the delivery device in the endoscope. The springs are further selected so that the manual forces needed to overcome the springs to advance pusher rod **94** and to retract sliding cutter sleeve **30** are within acceptable ranges.

In a further embodiment shown in FIGS. 159 – 162, a control handle **90'** provides a means of cinching the suture clip components, releasing the cinched suture clip and severing the suture tails with a single action. In this embodiment, a handle main body **90a** extends distally and terminates as collet cage **2**. An outer handle sleeve **90b** is provided about main body **90a**, extends distally and terminates as sliding sleeve **30**. To secure plug **62** into ring **60**, a distally directed force is applied to cinch handle **92'** to overcome the force of second return spring **106** which has an axial pre-bias load in tension. Distal advancement of cinch handle **92** relative to handle main body **90a** causes second return spring **106** to engage a proximal end of a ramrod **94a** and cause the distal advancement of ramrod **94a** into a proximal end of pusher **94**. Distal advancement of pusher **94** causes engagement and distal advancement of plug **62**. Second return spring **106** is of sufficient resiliency to resist

compression while moving ramrod **94a** distally to effectuate the insertion of plug **62** into ring **60**.

A restraining force to hold outer handle sleeve **90b** and sliding sleeve **30** in a stationary position relative to advancing ramrod **94a** and cinch handle **92** is provided by a user's fingers engaged in finger rings **5a**, mounted to a proximal end of outer handle sleeve **90b**. Spring plunger **30a** provided at the proximal end of outer handle sleeve **90b**, engages cutout **30b** formed in handle main body **90a** to temporarily lock outer handle sleeve **90b** and main body **90a** together during distal advancement of ramrod **94a**. Spring plunger **30a**, biased in a radially extended position by a plunger spring **30d**, remains extended and in a locked position with respect to main body **90a**. Plunger spring **30d** have an axial pre-bias load in tension. Spring plunger **30a** may be compressed only when the distal angular face **16a** of cinch handle **92** has advanced distally to a point of tangency with angular face **19** of spring plungers **30a**. Distal movement of the distal angular face **16** drives spring plunger **30a** in a direction perpendicular to the central axis, a distance equivalent to the thickness **20a** of the wall of cinch handle **92**. At this point, the restraining forces provided by the user's fingers (in a proximal direction), acting on main body **90a** through finger rings **5a**, have been restrained. The locking action of spring plunger **30a** is an interaction of a radial surface **22a** with pusher face **21**. Alignment of angular face **19** with angular pusher face **21** results in continued radial outward motion of spring plunger **30a** with the continued distal motion of main body **90a**.

Main body **90a** continues distally with the application of palm pressure on cinch handle **92** and the relative opposite motion of finger rings **5a** (proximally). Suture **80** (not shown), lying in a path of sliding sleeve **30** is severed with the proximal travel of sliding sleeve **30**. Collet fingers **4** are now unrestrained and assume their biased open position releasing cinched plug **62** and ring **60**.

In the most retracted stage of sliding sleeve **30** and finger rings **5a**, a second spring plunger **23** drops into a second cutout **30c**. Second spring plunger **23** is maintained in a compressed state via second plunger spring **30e**. Second plunger spring **30e** has an axial pre-bias load in compression. Second spring plunger **23** remains in second cutout **30c** only with the application of a force by the user's thumb on the most outward end of second spring plunger **23**. This temporary locking feature is provided to maintain sliding sleeve **30** in its most proximal position to allow for

loading of plug **62** and ring **60** as described in detail herein. Release of the holding pressure automatically releases sliding sleeve **30** to affect a closure of the delivery system.

To operate this embodiment of the suture clip delivery system, following the loading of a suture clip assembly and the threading of sutures through ring **60** described below, the entire delivery device is advanced through the endoscope to the sutured tissue site. Next, cinch handle **92** is advanced toward collet cage handle **98** to cinch plug **62** into ring **60** so that suture **80** is captured between the mating surfaces of a plug distal shaft **68** and the inner walls of ring **60**. Following completion of the cinching step, sliding sleeve handle **102** is retracted toward collet cage handle **98** to simultaneously sever the unused ends of suture **80** and to allow collet fingers **4** to spring open and release the suture clip assembly. To complete the procedure, the suture clip delivery system is partially retracted so that the suture clip is clear of the delivery system distal end. Prior to full retraction, sliding sleeve handle **102** is advanced to move collet fingers **4** into a closed position to allow for the full retraction of the suture clip delivery system out of the endoscope. With the spring embodiment of the handle (FIG. 164), release of the users' grip on sliding sleeve handle **102** allows first return spring **105** to relax thereby advancing sliding sleeve handle **102** and sliding cutter sleeve **30** to a preferably fully advanced position.

The suture clips used with the suture clip delivery catheter and/or endoscopic system described herein, have plugs with heads. In another embodiment as shown in FIG. 149, plug **62** has distal shaft **68** that is adapted to frictionally engage the inner walls of ring **60** and a head **64** that has preferably two suture receiving bores **70** formed toward the perimeter of the head **64**. This configuration provides a suture clip plug that decreases the effort needed to advance the plug over the ends of a suture before loading into the suture clip delivery device.

In a preferred embodiment shown in FIGS. 150-152, the inner and outer walls of ring **60** are radiused at the ends **74** to facilitate the insertion of distal shaft **68** into ring **60**. More importantly, the radiused ends provide strain relief for the sutures **80** when compressed between the plug **62** and ring **60**. To further facilitate insertion, distal shaft **68** is formed with a tapered distal tip **72**. Alternatively, a reduced neck distal tip **72a** can be employed as shown in FIG. 153. Although interlocking features can be incorporated into the plug and clip components, it has been found that such

features can lead to suture fraying, premature fracturing and failure. Use of tapered or reduced tipped plugs 62 allow for a preferred gradual reduction in compression. It has been found that suture capture is optimized and suture destruction is minimized when a distally decreasing taper leading end is used on plug 62 with a proximally increasing diameter of plug 62 to exceed the net diameter of the suture 80 in a captured state plus the diameter of plug 62 by at least .002 inches. The preferred materials used to make plug 62 and ring 60 are polyetherether ketone (PEEK) 450G, PEEK-Optima™ LT or polyethylene terephthalate (PET).

As previously stated, suture 80 is held via friction between plug 62 and ring 60. For example, a .009 inch thick suture is captured in a .003 inch gap between plug 62 and ring 60 so that the suture will remain captured with the application of a three pound load. The aforementioned radiused and tapered surfaces of plug 62 and ring 60 provide enough strain relief to prevent damage to suture 80 when subjected to the three-pound load.

A further suture clip embodiment employs a head with a proximal surface that is convex as shown in FIG. 148. Preferably, the distal end of inner pusher 24 is provided with a concave surface to matingly engage the convex surface of plug head. This configuration aids with the axial alignment of the ring and plug during distal advancement and engagement.

To load the suture clip assembly into collet cage 2, a suture clip loader device 110 is provided as shown in FIGS. 154-156. Loader device 110 comprises a loader housing 112 that is substantially cylindrical in shape and a plunger 114 that is also substantially cylindrical in shape. Loader housing 112 has a collet cavity 116 formed in a first end 118 that is dimensioned to receive collet cage 2. Collet cavity 116 has a cavity end 120 tapered to facilitate insertion of collet cage 2. Formed on diametrically opposed surfaces of a sidewall of loader housing 112 are finger grooves 122 that provide a stable holding surface for manipulating loader housing 112 during a suture clip loading procedure. A loader hypotube 124 is secured with an adhesive 126 (preferably cyanoacrylate Loctite® 4013 or 4014) to a loader hypotube shoulder 123 and a bore formed along the longitudinal axis of loader housing 112. Loader hypotube 124 extends from a second end 130 of loader housing 112 to at least partially within collet cavity 116 and is dimensioned to receive at a distal hypotube end 125, the

tapered distal tip **72** of plug **62**. A transverse groove **128** is formed proximal to second end **130** of loader housing **112**. The function of groove **128** will be discussed below.

Plunger **114** comprises a plunger head **132** and a plunger rod **134** secured via friction fit or adhesive in a bore formed along a longitudinal axis of plunger head **132**. Plunger rod **134** is sized to freely slide within hypotube **124**. Extending from a first plunger end **136** of plunger head **132** is tab **138**. A top surface of tab **138** is contoured like, and coplanar with, the outer surface of plunger head **132** while a bottom surface is substantially flat and oriented substantially perpendicular to first plunger end **136**. Extending downwardly from a distal end of tab **138** is a flange **140** that is shaped to conform to the shape of groove **128**. Optionally, plunger head **132** can be formed with a radiused second plunger end **142** for ease of handling.

The cross-sectional diameter of plunger head **132** is sized so that the distance between the bottom surface of tab **138** and the most distant point on the cross-sectional circumference of plunger head **132** is substantially equal to the cross-sectional diameter of loader housing **112**. When plunger rod **134** is inserted into hypotube **124**, the bottom surface of tab **138** rides along the outer surface of loader housing **112**. Because flange **140** extends below the bottom surface of tab **138**, advancement of plunger **114** toward loader housing **112** results in flange **140** engaging groove **128** and temporarily locking in the distance between plunger **114** and loader housing **112**. In this orientation, a distal end of plunger rod **134** does not reach distal hypotube end **125** so that plug **62** can be received in hypotube end **125**.

The preferred materials for the suture clip loader device **110** components are as follows. Plunger head **132** is made from Delrin® and is preferably white. Plunger rod **134** is made from 304V stainless steel. Loader hypotube shoulder **123** is made from 304 stainless steel. Loader housing is made from polycarbonate GE Lexan® 104-1111 and is preferably clear to allow for an unobstructed view of hypotube end **125**. Hypotube **124** is made from polyetherether ketone (PEEK) 450G.

The operation of suture clip loader device **110** is as follows. The process begins by placing ring **60** over hypotube **124**. Next, the distal tip **72** of plug **62** is inserted into hypotube end **125** until it is snugly secured to hypotube **124**. At this point, plunger **114** is secured to loader housing **112** via the engagement of flange **140** to groove **128**.

With collet cage 2 extending from the distal end of an endoscope, sliding sleeve 30 is retracted to allow collet fingers 4 to spring into an open position. Collet cage 2 is advanced over hypotube 124 and ring 60 until the distal end of collet cage 2 engages a bottom of collet cavity 116. Once the suture clip components have been correctly encapsulated by collet fingers 4, force is applied to plunger 114 to overcome the locking engagement of flange 140 and groove 128. This enables plunger rod 134 to be advanced through hypotube 124 to contact and eject plug 62 into collet cage 2. Proper ejection is assured when first plunger end 136 contacts second end 130 of loader housing 112. To capture ring 60 within collet cage 2, sliding sleeve 30 is advanced to move collet fingers 4 into a closed position about ring 60 and hypotube 124. Collet finger flanges 6 engage a distal face of ring 60 so that retraction of collet cage 2 from hypotube 124 results in ring 60 being retracted off hypotube 124 and secured within the distal end of collet cage 2.

It is important that plug 62 is maintained in the proximal end of collet cage 2 and that ring 60 is maintained in the distal end of collet cage 2. This is required to enable suture 80 to be threaded through ring 60 prior to cinching and final deployment of the suture clip assembly.

The next step in the procedure is to thread sutures previously secured to tissue through ring 60. To perform this procedure, a threader or suture loop tool 150 is used. As shown in FIGS. 173-175, threader 150 comprises a threader housing 152 that is substantially cylindrical in shape and preferably made from polycarbonate GE Lexan® 104-1111. Formed on diametrically opposed surfaces of a sidewall of threader housing 152 are threader finger grooves 160 that provide a stable holding surface for manipulating threader housing 152 during a suture threading procedure. Affixed to a bore formed along the longitudinal axis of threader housing 152 is suture loop hypotube 154. An adhesive 158 such as cyanoacrylate Loctite® 4013 (clear) is used to secure suture loop hypotube 154 (preferably made from 304 stainless steel), to threader housing 152. A suture loop 156 preferably made of two thin 304v stainless steel wires is secured inside suture loop hypotube 154 and extends beyond a distal end 162 of suture loop hypotube 154. A suture loop distal end 164 is formed into a diamond shape by overlapping the stainless steel wires. Preferably, a tip of the suture loop distal end is formed by overlapping the wires at least twice.

To thread suture **80** through ring **60**, suture loop **156** of threader **150** is inserted into suture slot **34** of sliding sleeve **30**, advanced through ring **60** and through the distal end of collet cage **2**. Suture **80** is inserted into the diamond-shaped suture loop distal end so that it engages and preferably becomes entangled with the intertwined distal tip of suture loop distal end **164**. To thread suture **80** through ring **60**, threader **150** is retracted out of suture slot **34**. Suture **80** is then removed from threader **150**. The suture clip assembly is now ready for cinching and deployment as described above.

In an alternate embodiment, threader **150** comprises a vacuum-actuated nozzle **150'** made from a pliable polymeric or elastomeric material. As shown in FIGS. 176 and 177, a nozzle head **170** is formed at the end of a vacuum hose **168** and adapted to conform to the contoured shape of collet cage **2**. A proximal end of vacuum hose **168** (not shown) is attached to a vacuum source (not shown). In a further embodiment shown in FIGS. 178 and 179, nozzle head **170** is formed with nozzle ears **170'** that preferably extend about and beyond collet cage **2** to enhance the ease with which the nozzle head can be secured against suture slot **34**, again with either finger or forceps pressure.

To operate nozzle **150'**, nozzle head **170** is maintained against suture slot **34** with either finger pressure or pressure exerted with forceps while a vacuum is applied. The vacuum draws suture **80** through ring **60** and out of collet cage **2** via suture slot **34**. The vacuum is then released, nozzle head **170** is removed from collet cage **2** and suture **80** is grasped and pulled a desired amount through ring **60** and collet cage **2**.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments and equivalents may be apparent to those who are skilled in the art without departing from its spirit. Having thus described the invention what we desire to claim and secure by letters patent is:

Claims

1. A suture clip delivery catheter comprising:
a control handle;
a collet having a body and a plurality of collet fingers extending from a distal end of the body;
a hypotube connecting the control handle to the collet;
an outer sleeve situated coaxially about the collet such that the sleeve freely slides along a longitudinal axis; and
a pusher situated coaxially within the collet that freely slides along a longitudinal axis of the delivery catheter.
2. The catheter of claim 1 wherein the plurality of collet fingers further comprise flanges extended radially inwardly from a distal end of each of the plurality of collet fingers.
3. The catheter of claim 2 wherein at least one of the plurality of collet fingers has a ramp formed on an inside wall that tapers radially inwardly from a proximal to a distal end such that the combination of the collet fingers, ramp and flanges define a suture clip cage.
4. The catheter of claim 2 wherein the flanges are radiused on outer and inner distal edges.
5. The catheter of claim 1 wherein each of the plurality of collet fingers has sidewalls that define finger slots.
6. The catheter of claim 5 wherein the outer sleeve has portions defining at least one suture slot situated proximal to a distal end of the sleeve.

7. The catheter of claim 6 wherein the sleeve has further portions defining an alignment slot situated proximal to the suture slot.
8. The catheter of claim 7 wherein the collet has an alignment pin formed on an outer collet wall adapted to engage and slide within the alignment slot such that at least one of the finger slots radially aligns with the suture slot.
9. The catheter of claim 8 wherein the at least one finger slot longitudinally aligns with at least a portion of the suture slot.
10. The catheter of claim 2 wherein a proximal face of the flanges forms an inclusive angle with a longitudinal axis of an adjoining collet finger of from about 90° to about 135°.
11. A suture clip delivery catheter comprising:
 - a collet having a body and a plurality of collet fingers extending from a distal end of the body;
 - an outer sleeve situated coaxially about the collet such that the sleeve freely slides along a longitudinal axis;
 - a first pusher situated coaxially within the collet that freely slides along a longitudinal axis; and
 - a second pusher situated coaxially about the first pusher and coaxially within the collet that freely slides along a longitudinal axis.
12. The catheter of claim 11 wherein the plurality of collet fingers further comprise flanges extended radially inwardly from a distal end of each of the plurality of collet fingers.

13. The catheter of claim 12 wherein at least one of the plurality of collet fingers has a ramp formed on an inside wall that tapers radially inwardly from a proximal to a distal end such that the combination of the collet fingers, ramp and flanges define a suture clip cage.

14. The catheter of claim 12 wherein the flanges are radiused on outer and inner distal edges.

15. The catheter of claim 11 wherein each of the plurality of collet fingers has sidewalls that define finger slots.

16. The catheter of claim 15 wherein the outer sleeve has portions defining at least one suture slot situated proximal to a distal end of the sleeve.

17. The catheter of claim 16 wherein the sleeve has further portions defining an alignment slot situated proximal to the suture slot.

18. The catheter of claim 17 wherein the collet has an alignment pin formed on an outer collet wall adapted to engage and slide within the alignment slot such that at least one of the finger slots radially aligns with the suture slot.

19. The catheter of claim 18 wherein the at least one finger slot longitudinally aligns with at least a portion of the suture slot.

20. The catheter of claim 12 wherein a proximal face of the flanges forms an inclusive angle with a longitudinal axis of an adjoining collet finger of from about 90° to about 135°

21. The catheter of claim 13 wherein a distal end of the second pusher is tapered to matingly engage the ramp when the second pusher is distally advanced.
22. A method of delivering a suture clip to a sutured tissue site comprising the steps of:
- providing a collet having a body and a plurality of collet fingers extending distally from the body that define a suture clip cage;
 - providing a pusher inside the collet body in coaxial relation with the collet body;
 - providing a sliding sleeve in coaxial relation about the collet;
 - loading a suture clip plug having a proximal head and a suture clip ring into the suture clip cage;
 - advancing the suture clip cage to a sutured tissue site;
 - advancing the pusher inside the collet cage and engaging the suture clip plug;
 - engaging the suture clip plug with the suture clip ring to create a suture clip;
 - retracting the sliding sleeve to release the suture clip.
23. The method of claim 22 further comprising the steps of:
- providing suture slots in the sliding sleeve for receiving suture ends; and
 - threading ends of a suture through the suture slots and through the suture clip plug and suture clip ring.
24. The method of claim 22 further comprising the steps of:
- retracting the sliding sleeve to sever the suture ends.
25. A method of delivering a suture clip to a sutured tissue site comprising the steps of:
- providing a collet having a body and a plurality of collet fingers extending distally from the body that define a suture clip cage;

providing a first pusher inside the collet body in coaxial relationship;
providing a second pusher situated in coaxial relation about the first pusher and within the collet body;
providing a sliding sleeve in coaxial relation about the collet;
loading a suture clip plug having a proximal head and a suture clip ring into the suture clip cage;
advancing the suture clip cage to a sutured tissue site;
advancing the pusher inside the collet cage and engaging the suture clip plug;
engaging the suture clip plug with the suture clip ring to create a suture clip;
retracting the sliding sleeve to release the suture clip.

26. The method of claim 25 further comprising the steps of:
providing suture slots in the sliding sleeve for receiving suture ends; and
threading ends of a suture through the suture slots and through the suture clip plug and suture clip ring.

27. The method of claim 26 further comprising the steps of:
retracting the sliding sleeve to sever the suture ends.

28. The method of claim 27 comprising the further steps of:
advancing the second pusher to open the plurality of collet fingers to release the suture clip.

29. A suture clip loading device comprising:
a loading device housing with a hypotube affixed to a bore formed in the housing and,
a plunger having a rod dimensioned to slide freely within the hypotube.

30. A non-locking suture clip comprising:
a plug having a head and a shaft extending distally from the head, the shaft having a first diameter and the head having a second diameter greater than the first diameter;
a ring having an inner annular wall defining a through aperture extending from a proximal to a distal end of the ring, the through aperture having an aperture diameter greater than the first diameter wherein insertion of the shaft into the ring aperture forms an axial vacancy between the shaft and the ring portions defining the through aperture.
31. The suture clip of claim 30 wherein the shaft has a tapered distal end.
32. The suture clip of claim 30 wherein the shaft has a reduced neck distal end.
33. The suture clip of claim 30 wherein the axial vacancy is at least about .003 inches.
34. The suture clip of claim 30 wherein the axial vacancy is no greater than about .003 inches.
35. The suture clip of claim 30 further comprising a suture situated between the plug shaft and the ring wherein the suture has a diameter greater than the axial vacancy.
36. A suture clip assembly comprising:
means for securing a suture.

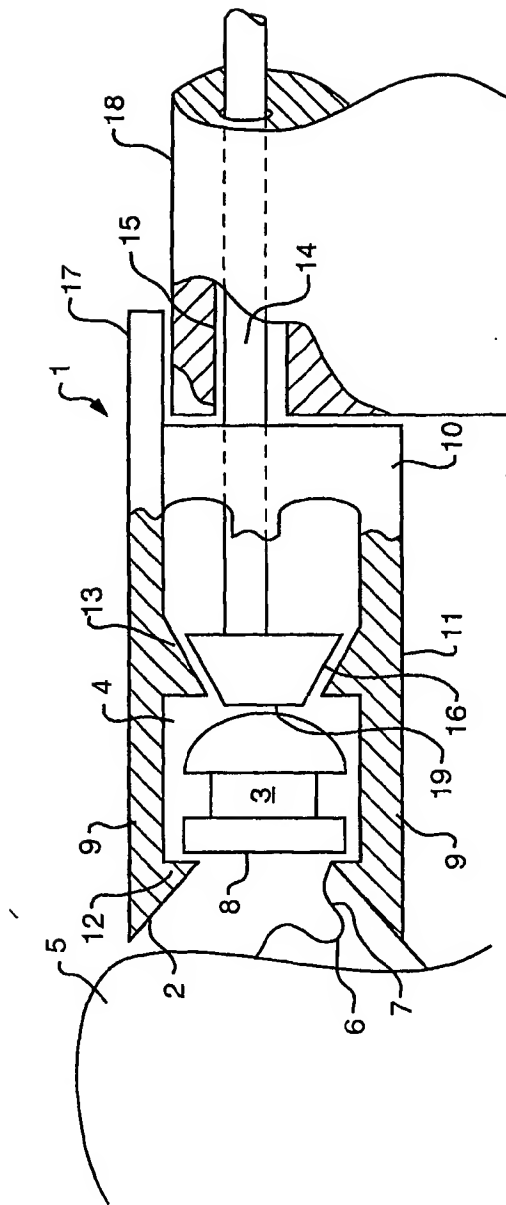


FIG. 1

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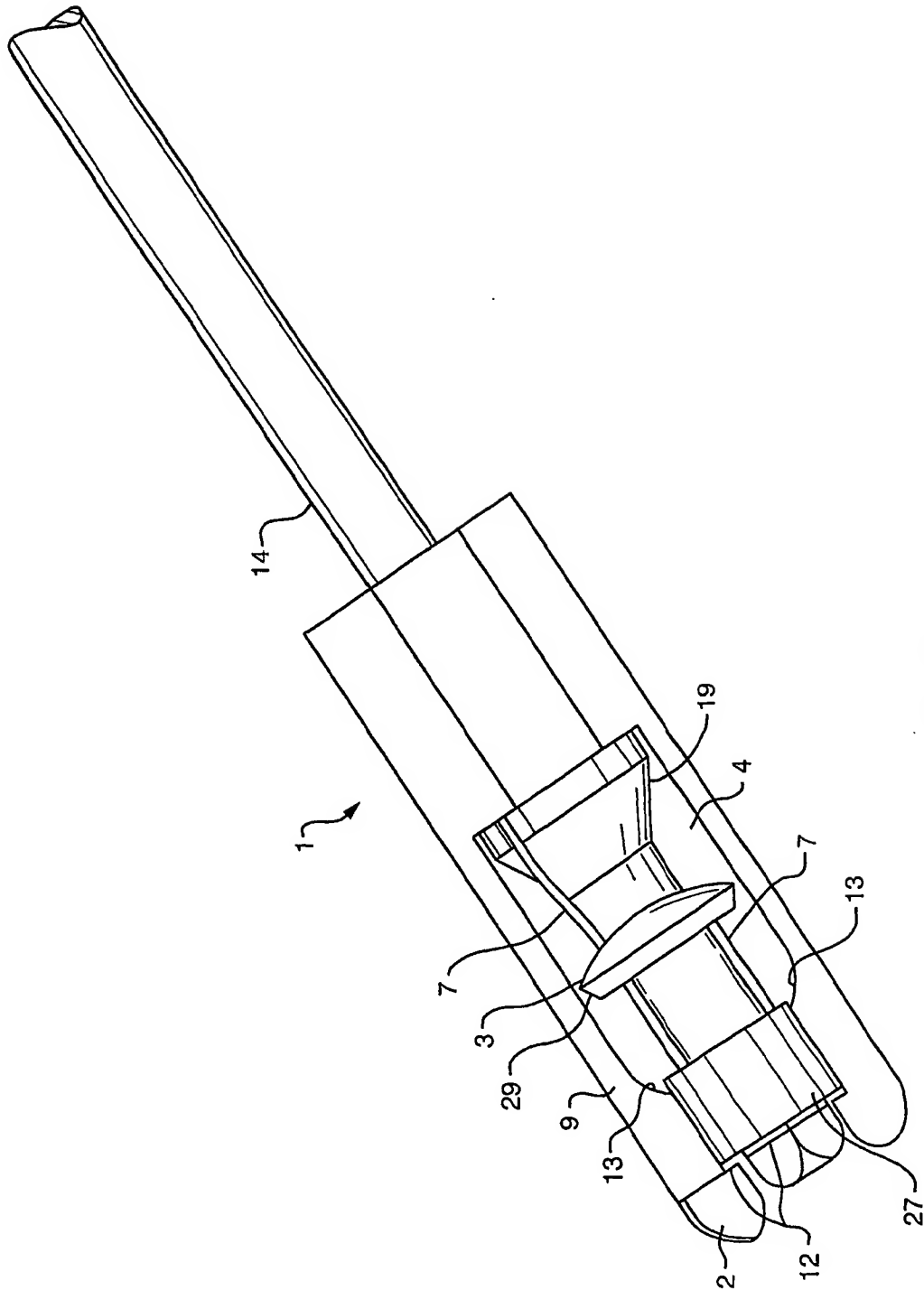
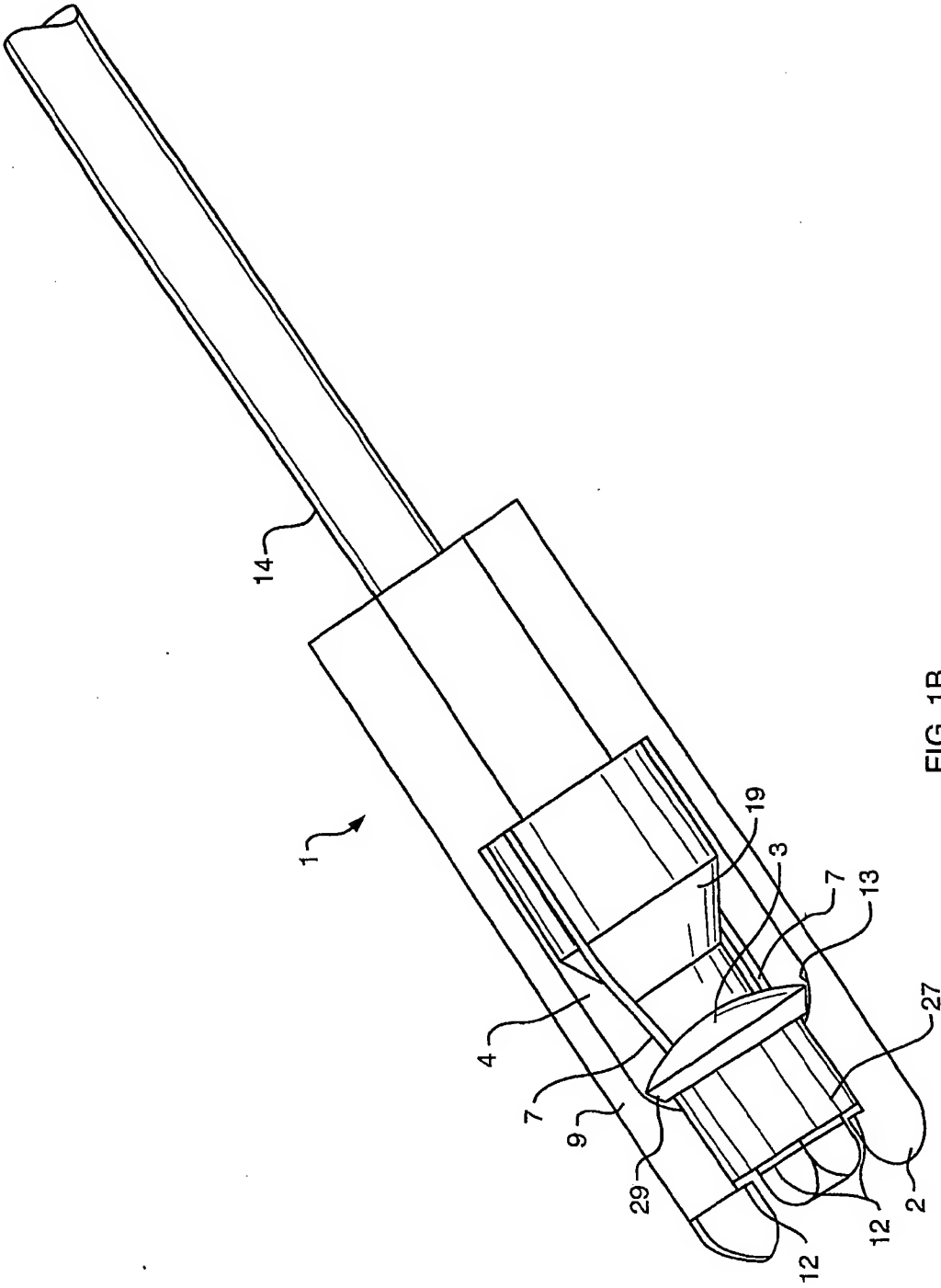


FIG. 1A

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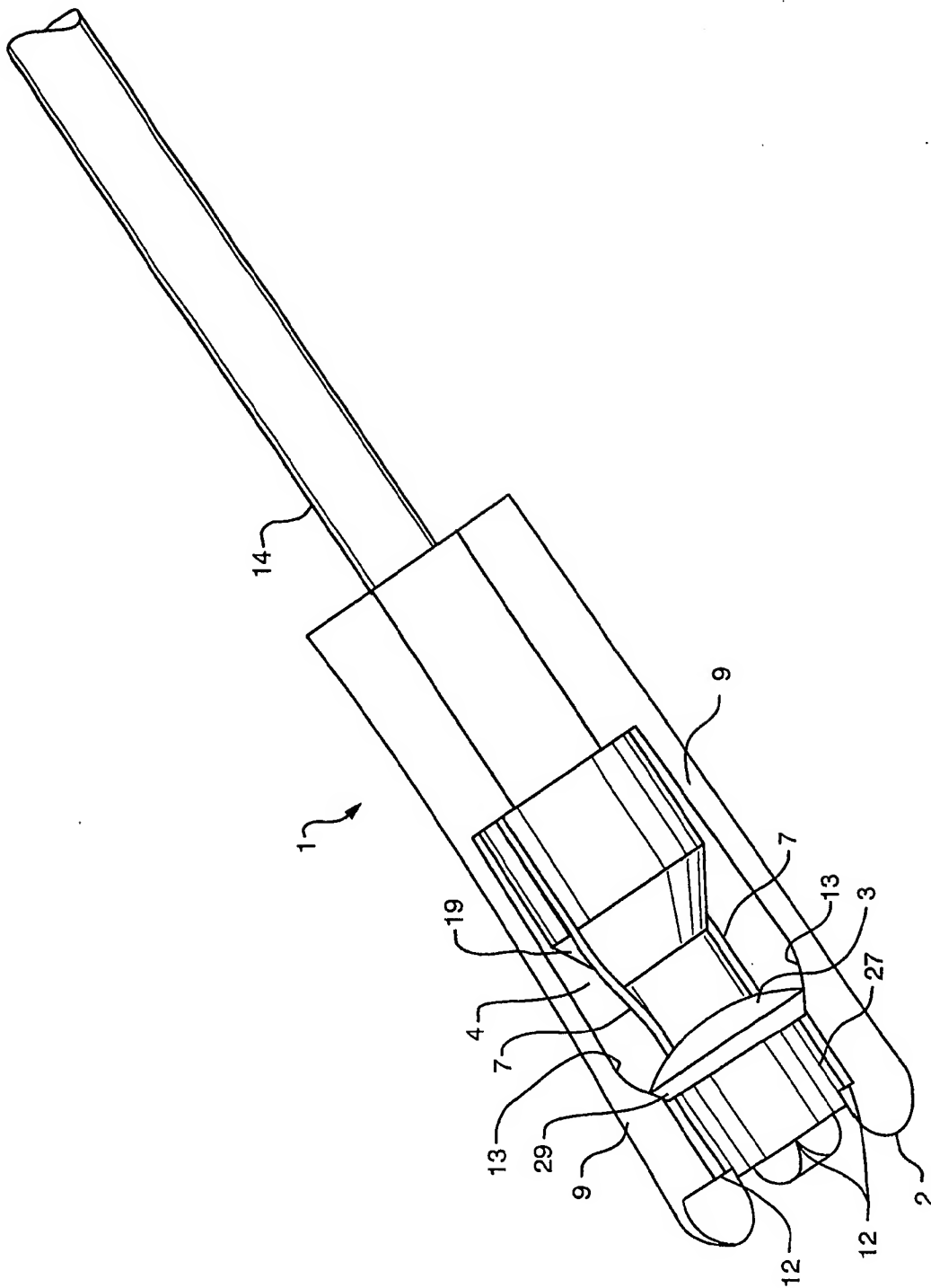
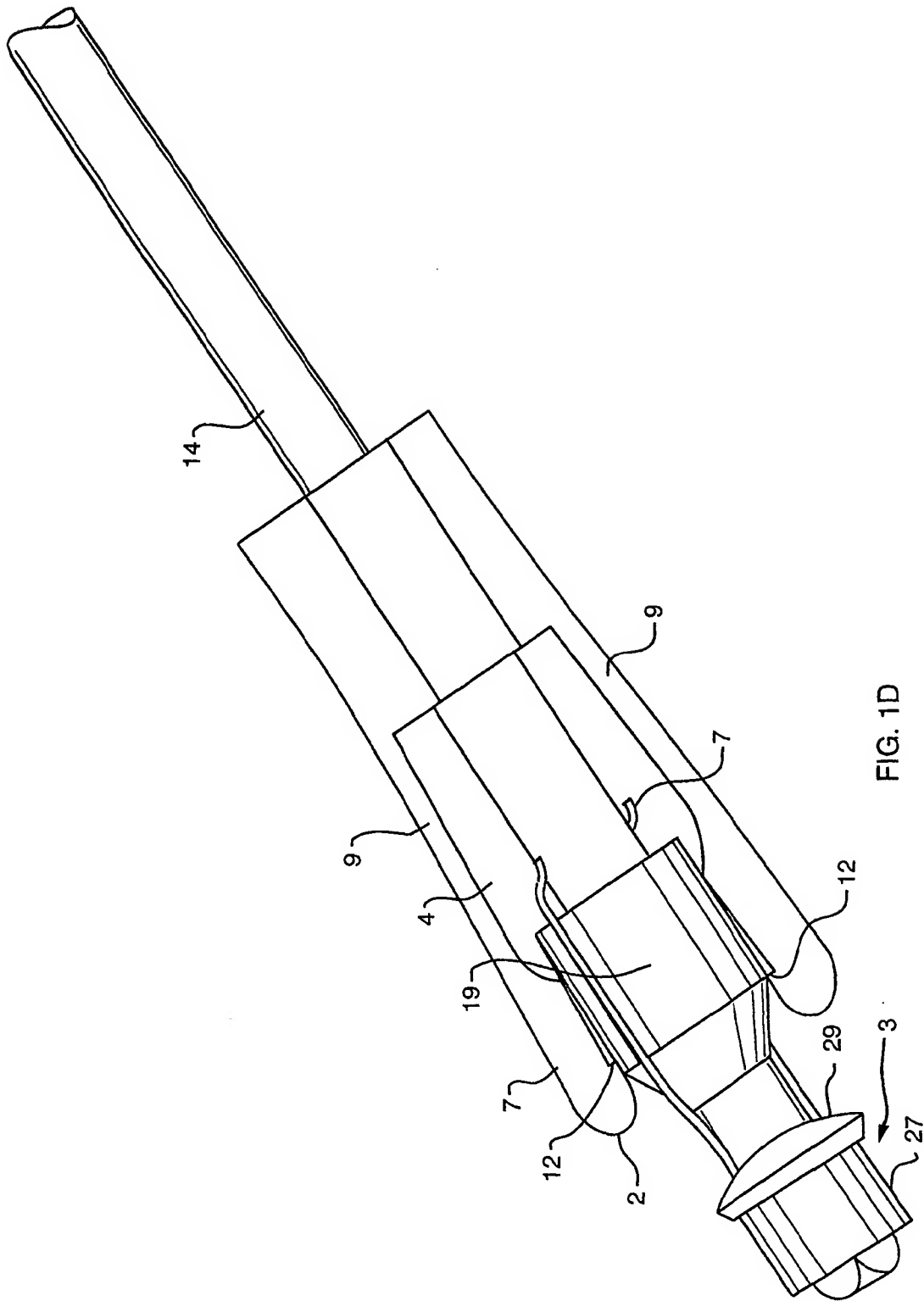


FIG. 1C

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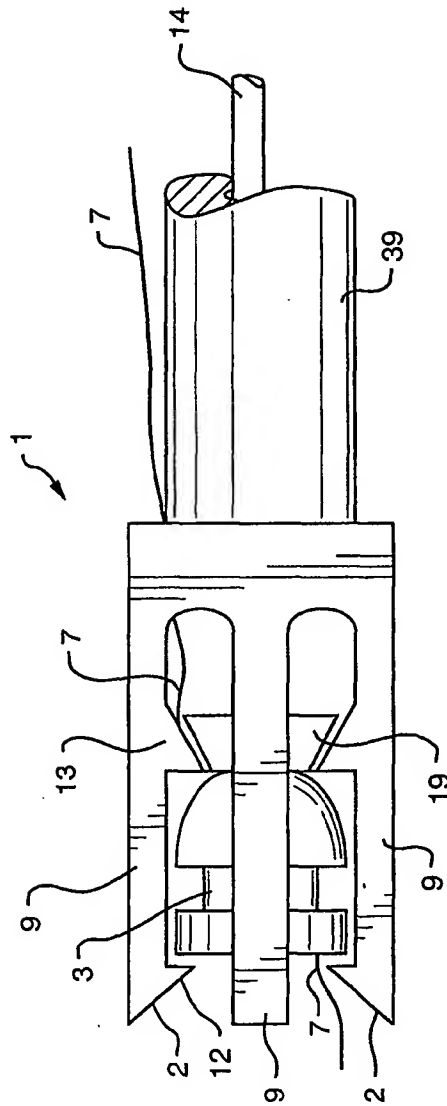


FIG. 2A

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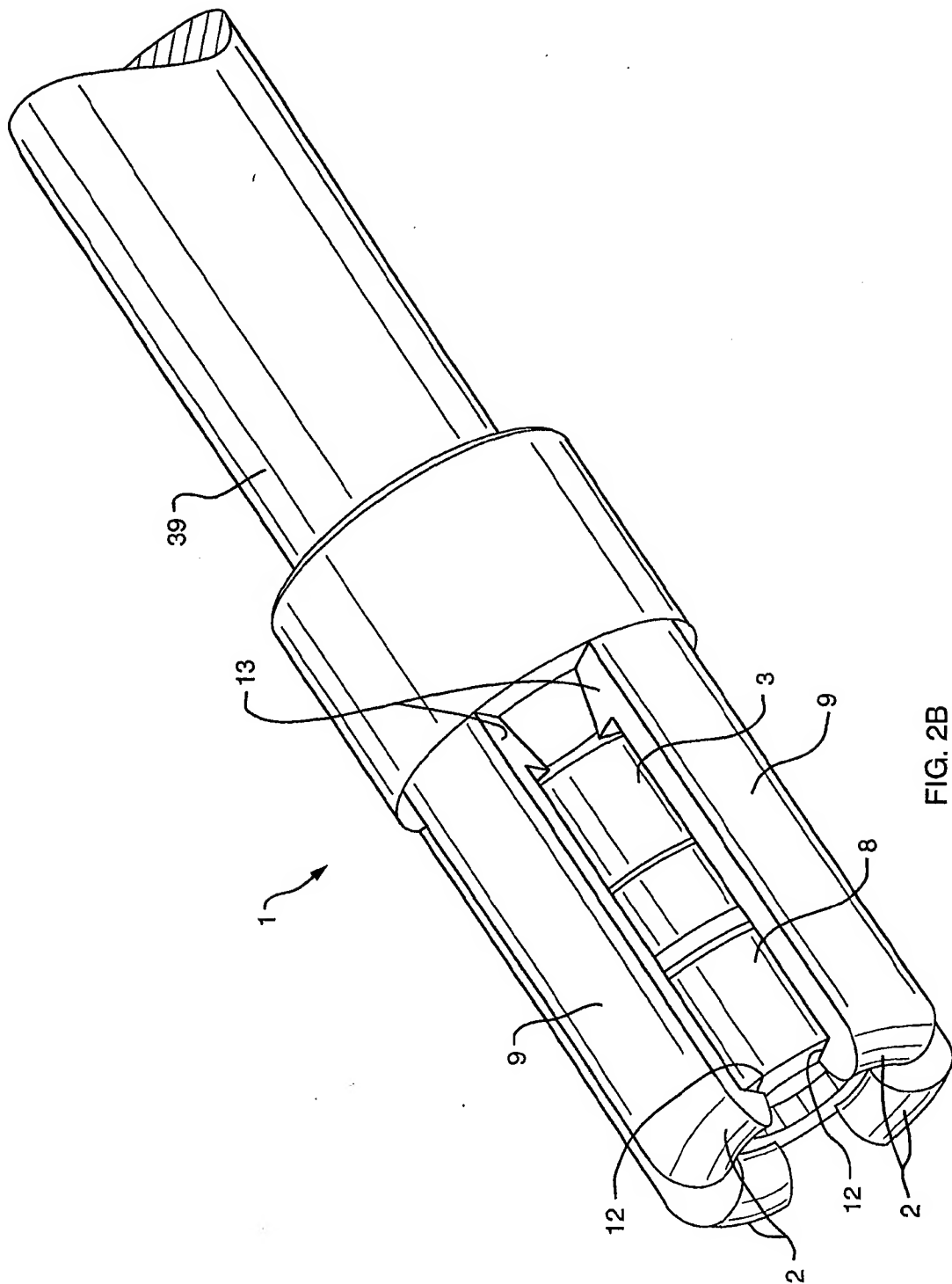


FIG. 2B

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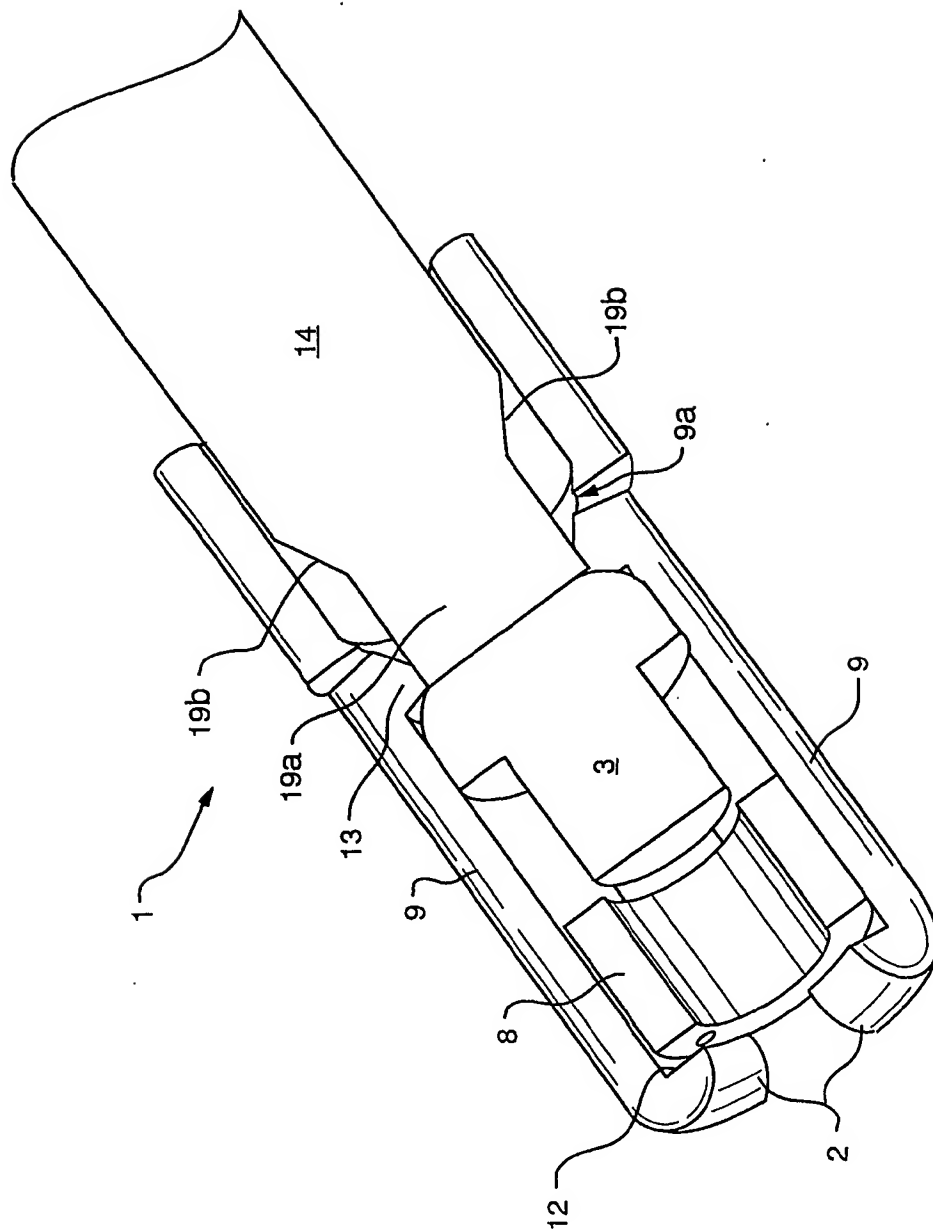


FIG. 2C

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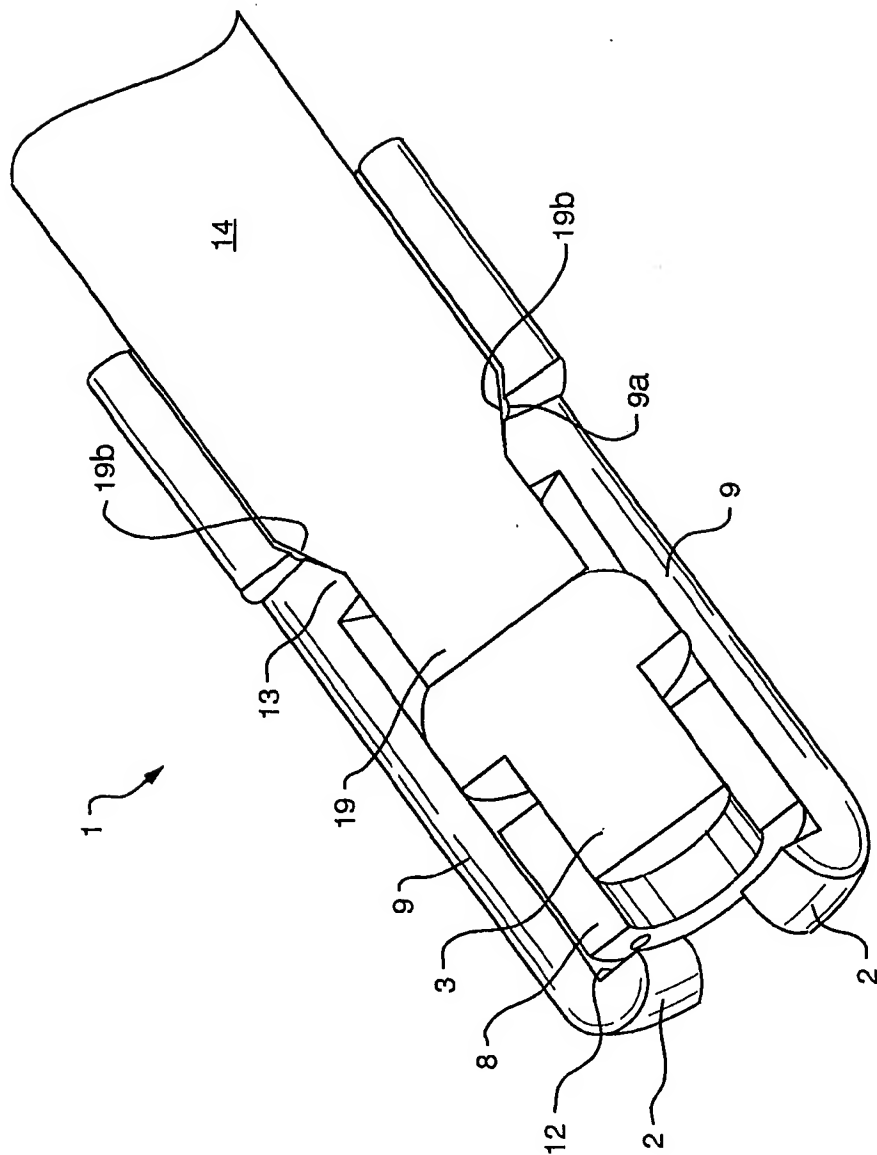


FIG. 2D

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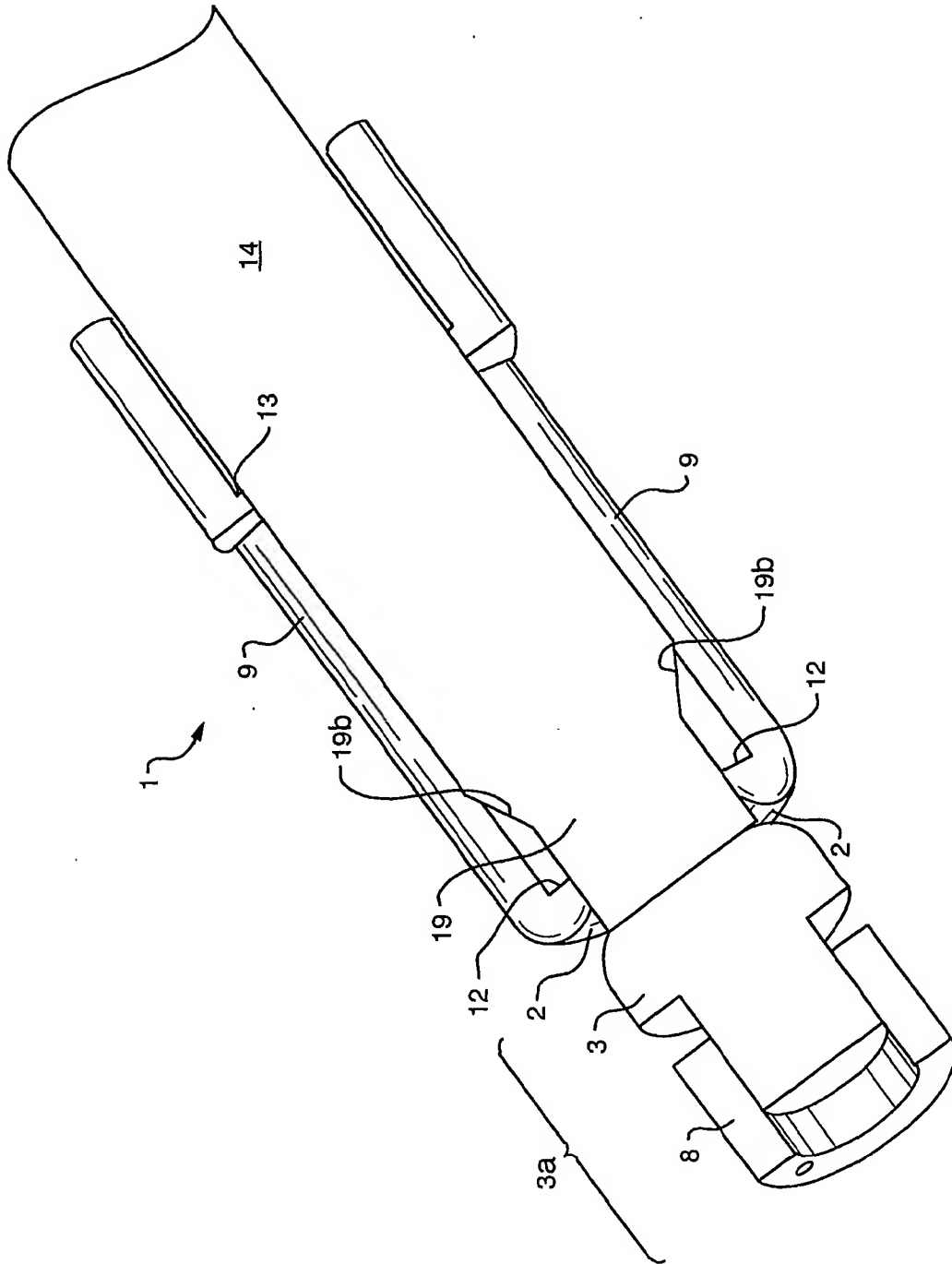


FIG. 2E

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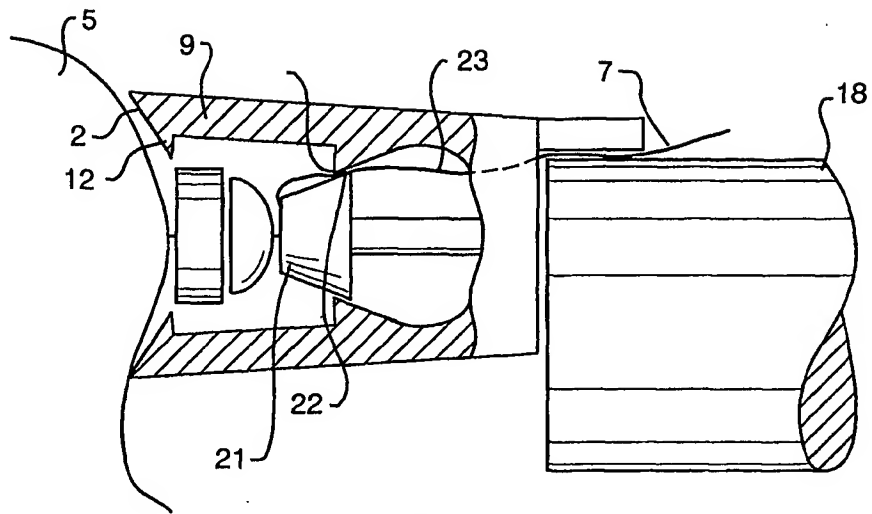


FIG. 3

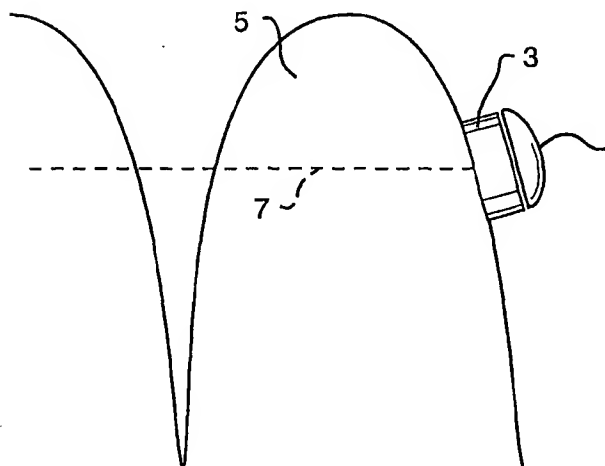


FIG. 5

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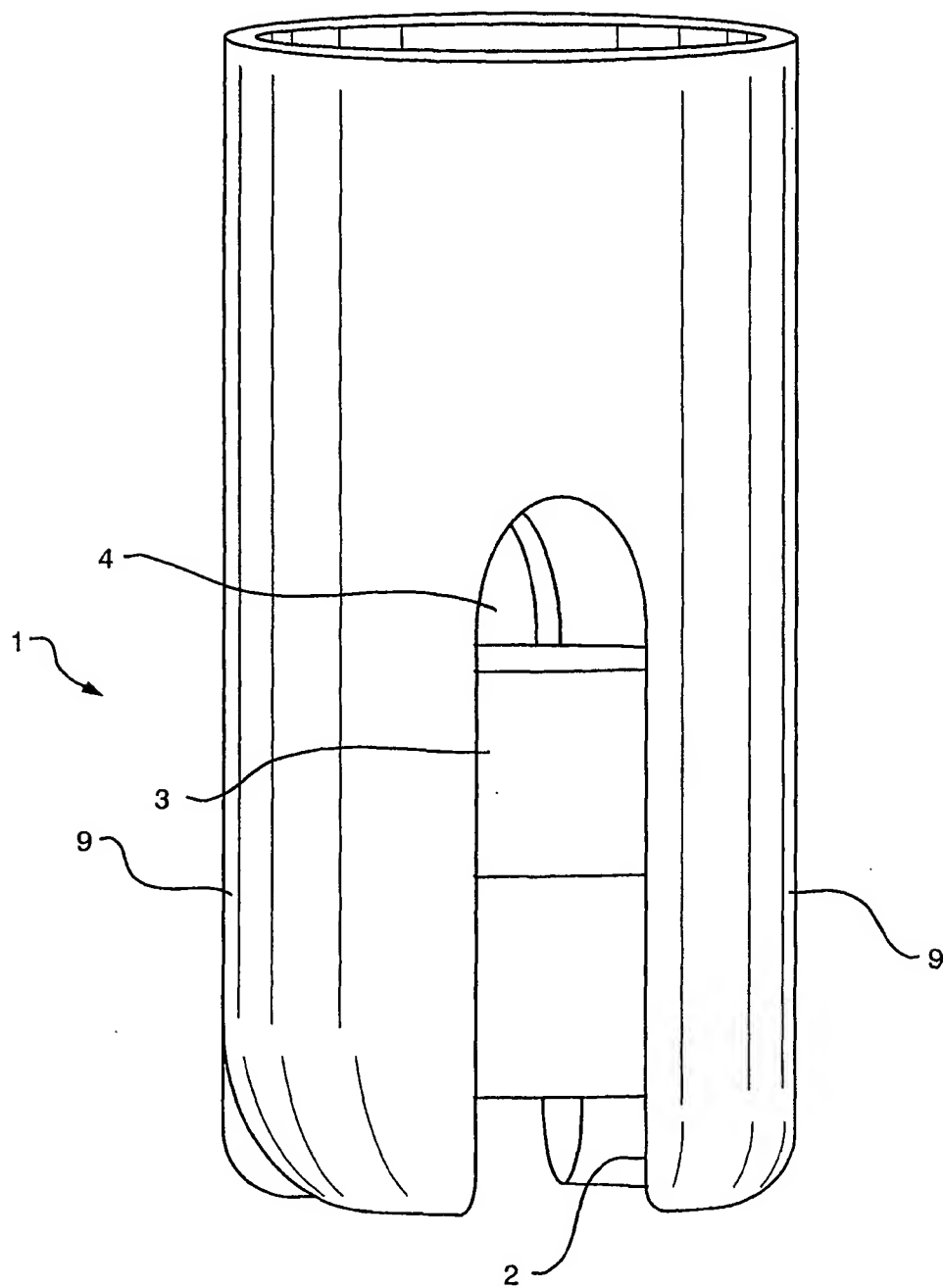


FIG. 4

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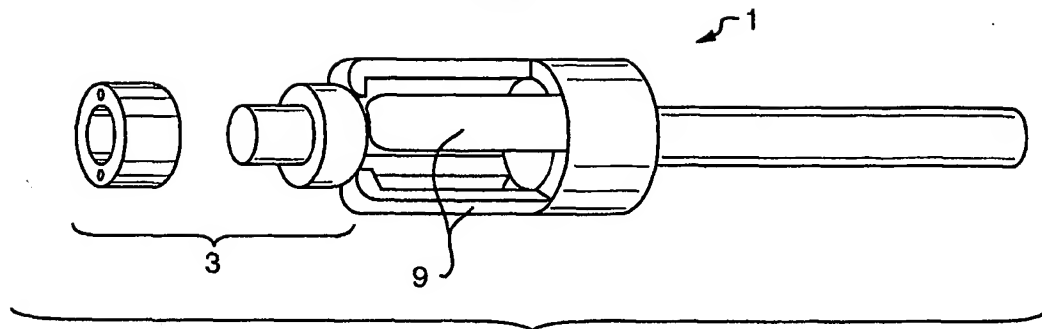


FIG. 4A

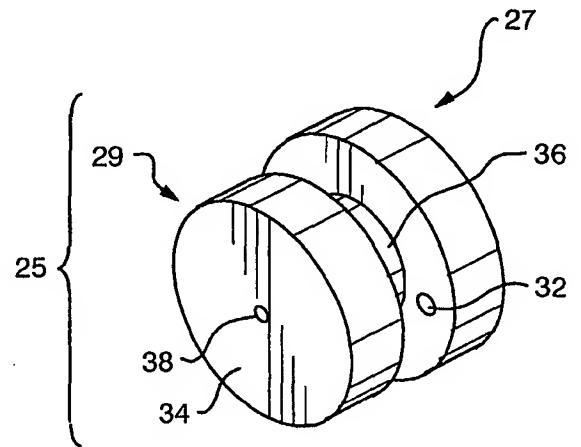


FIG. 10

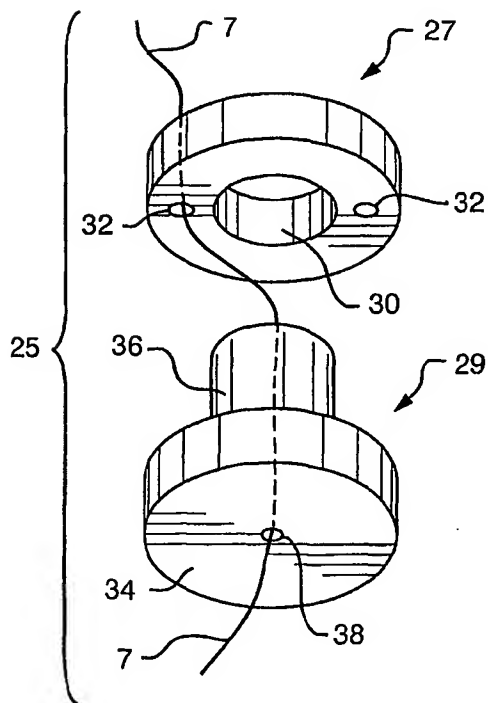


FIG. 6

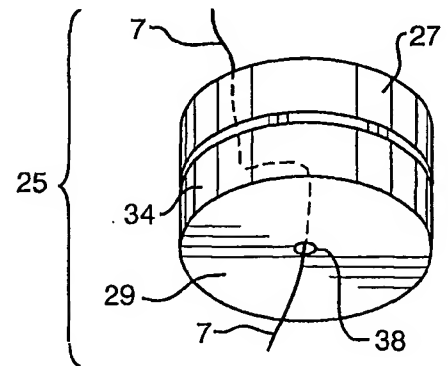


FIG. 7

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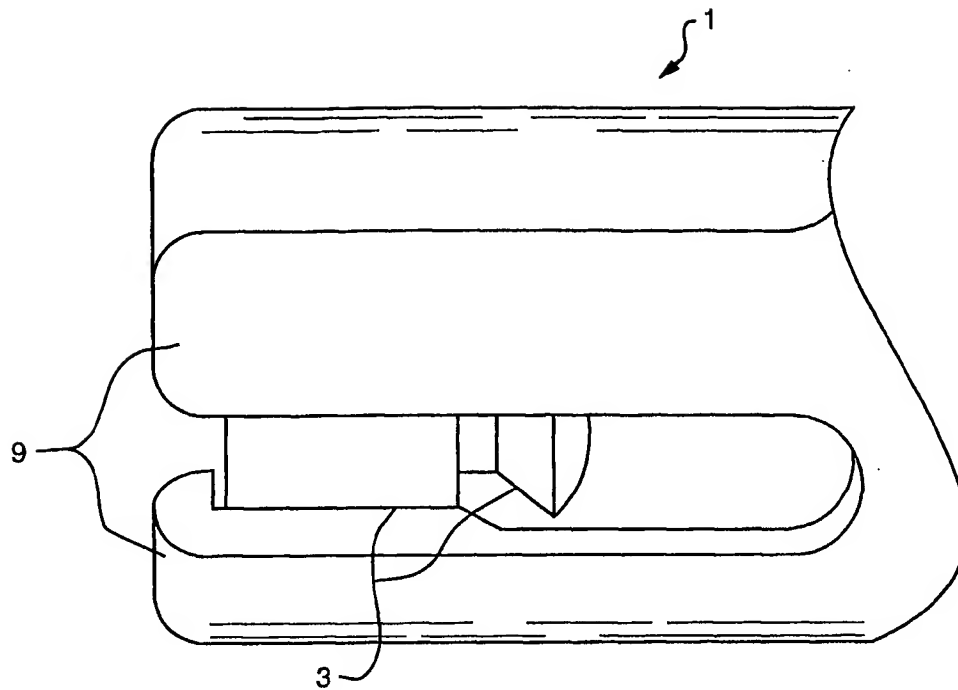


FIG. 8

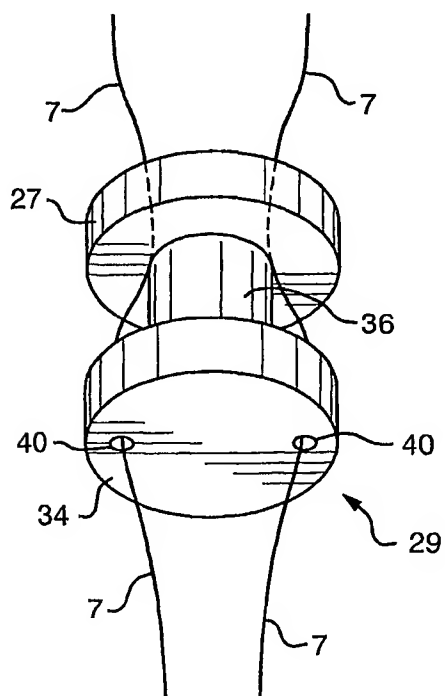


FIG. 9

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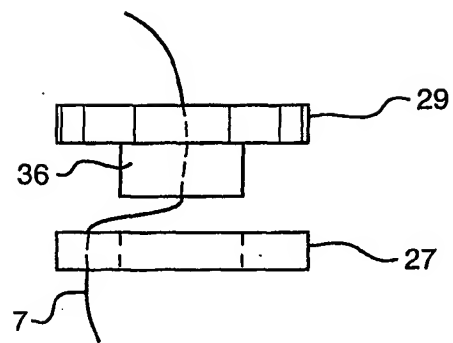


FIG. 11

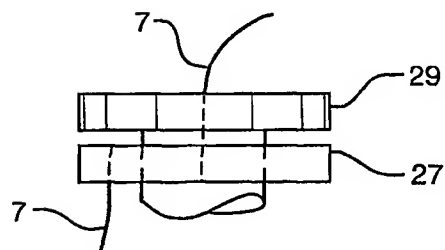


FIG. 12

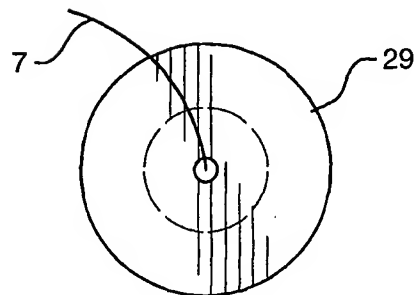


FIG. 13

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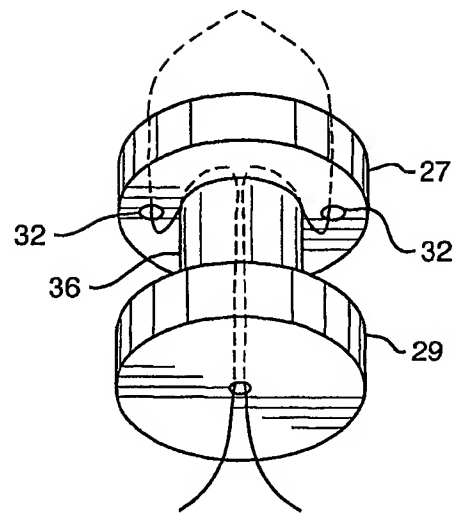


FIG. 14

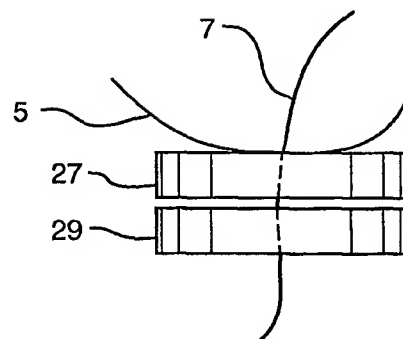


FIG. 15

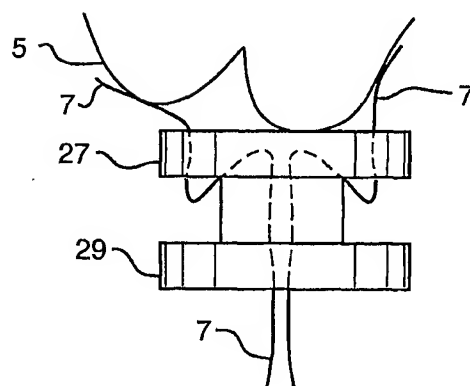


FIG. 16

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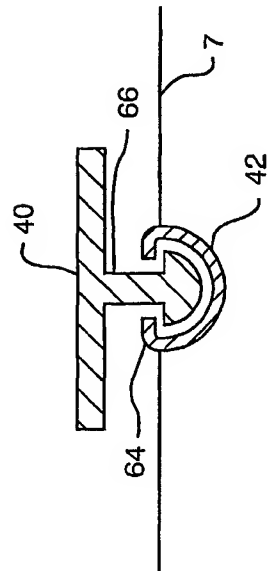


FIG. 17

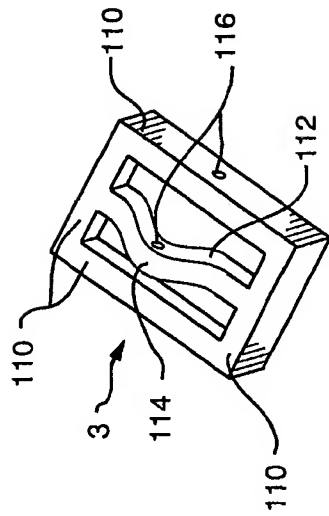


FIG. 18

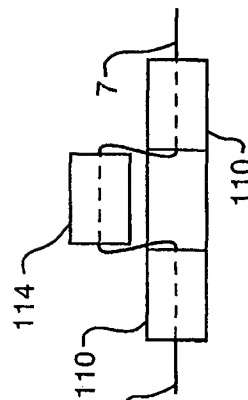


FIG. 19

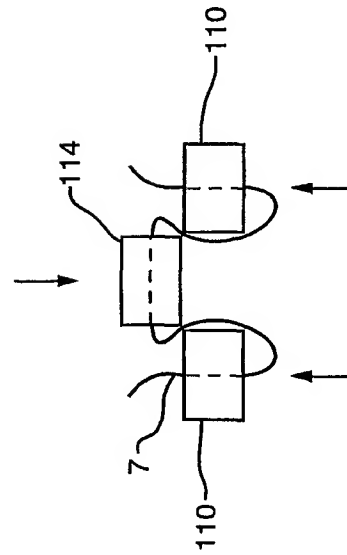


FIG. 20

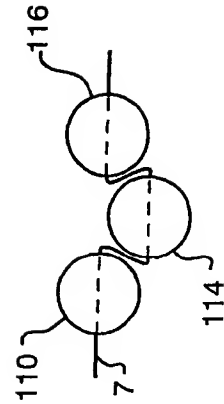


FIG. 21

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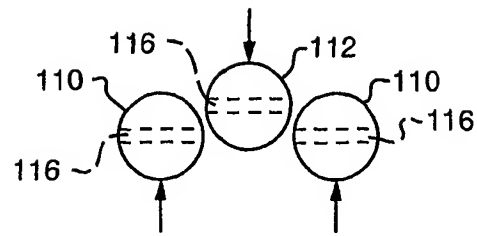


FIG. 22

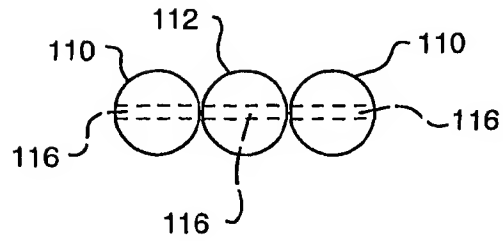


FIG. 23

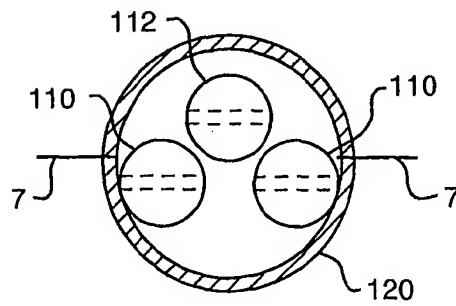


FIG. 24
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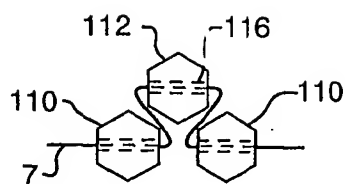


FIG. 25

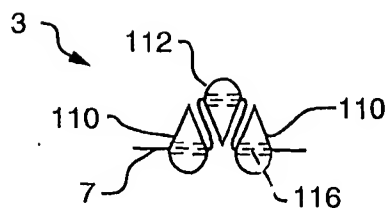


FIG. 26

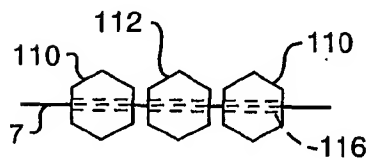


FIG. 27

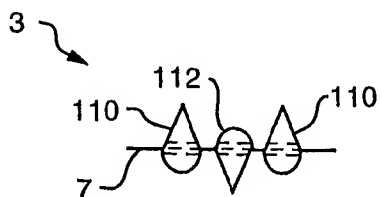


FIG. 28

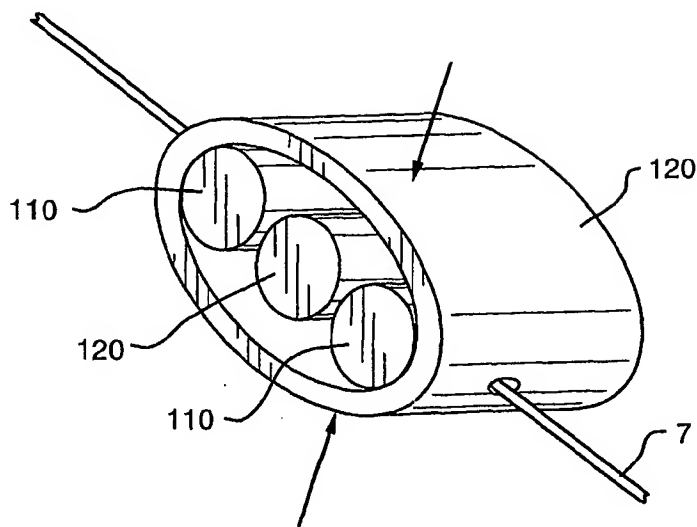
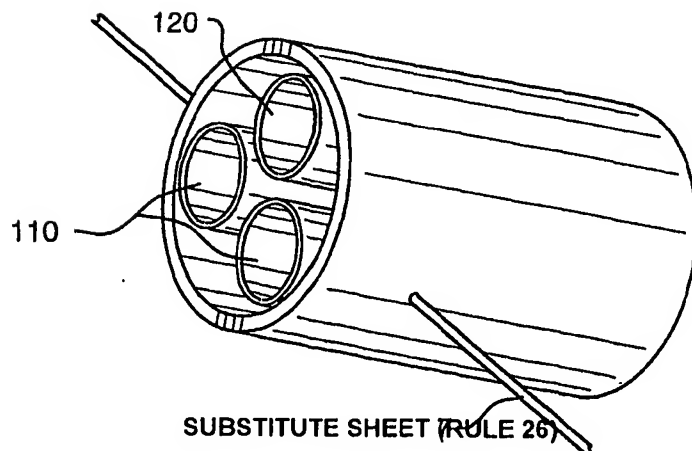


FIG. 33



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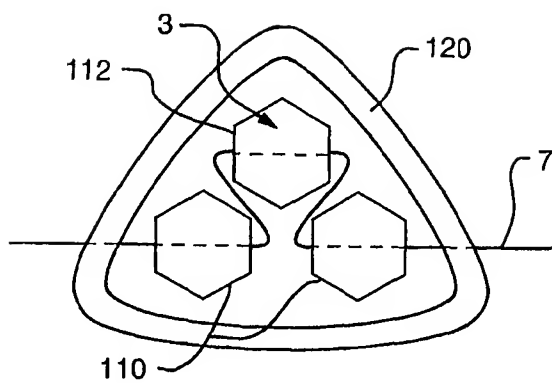


FIG. 29

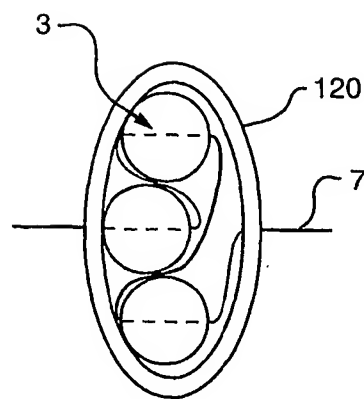


FIG. 30

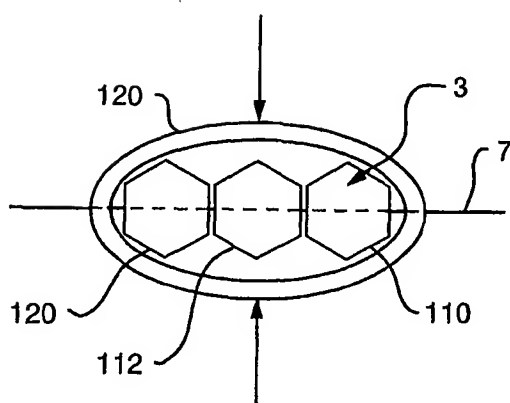


FIG. 31

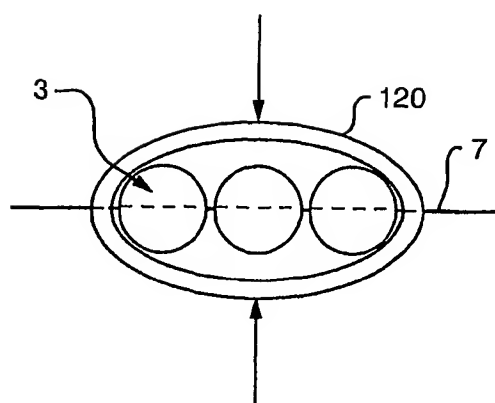


FIG. 32

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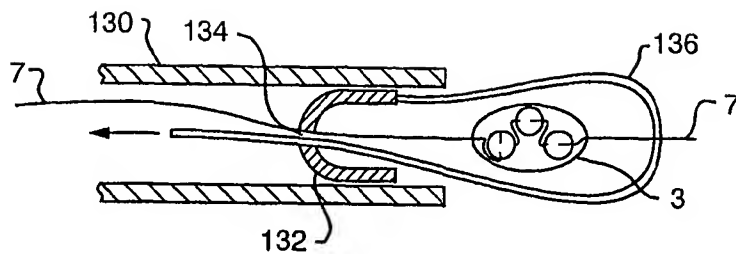


FIG. 35

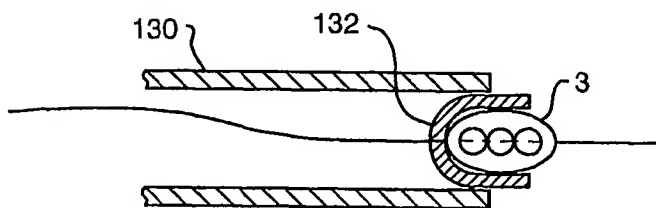


FIG. 36

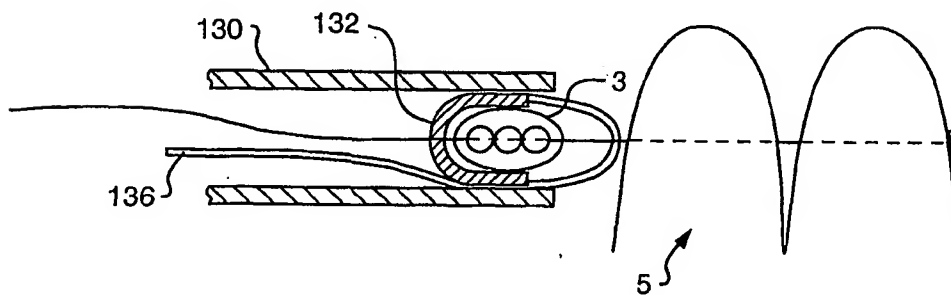


FIG. 37

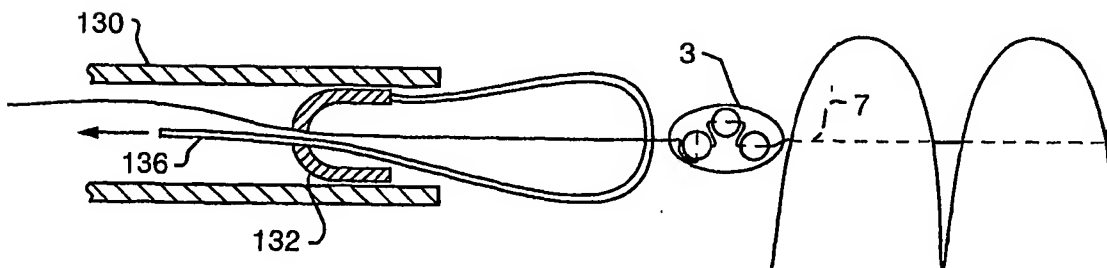


FIG. 38

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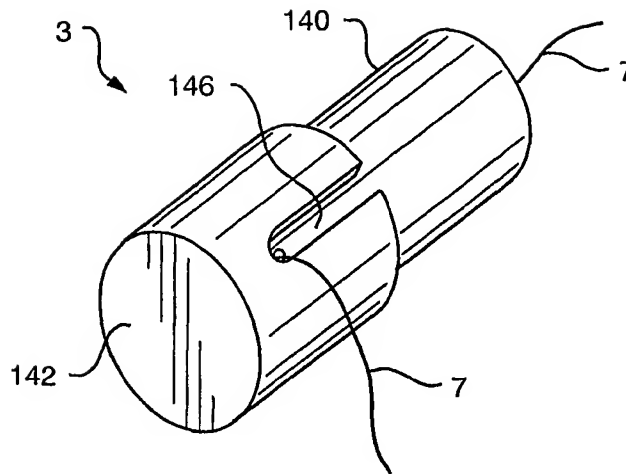


FIG. 39

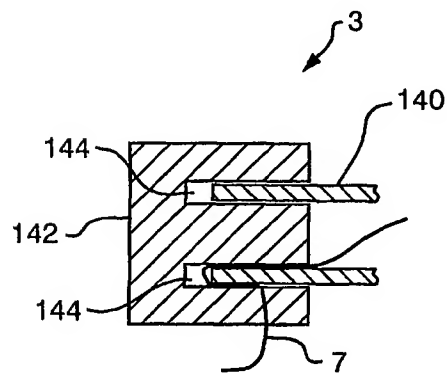


FIG. 40

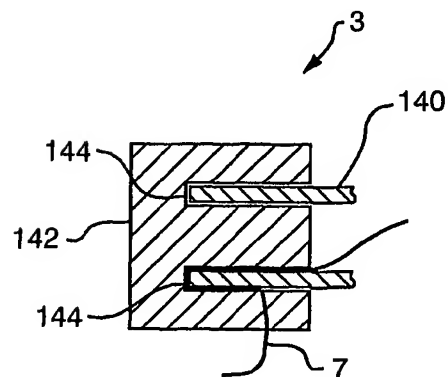


FIG. 41

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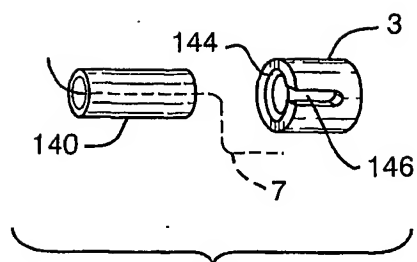


FIG. 42

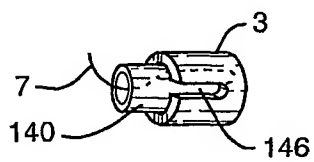


FIG. 43

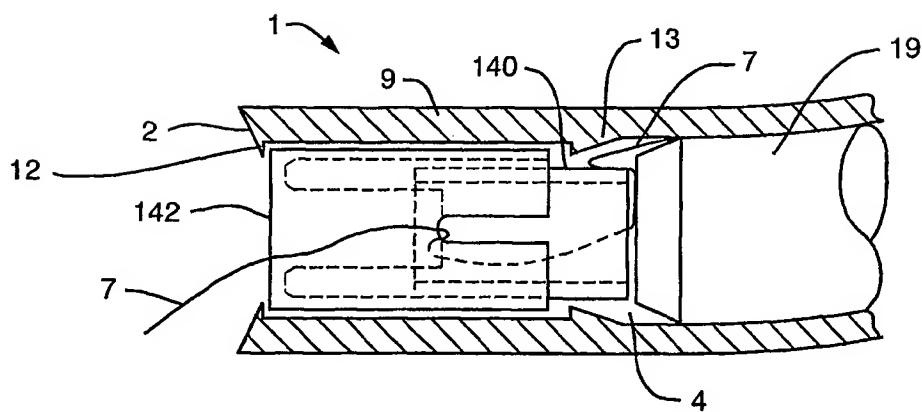


FIG. 44

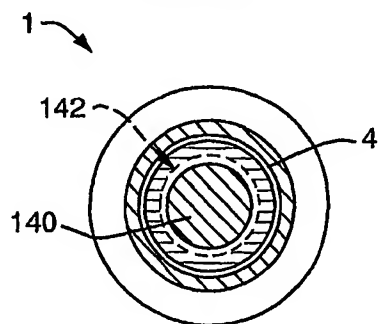
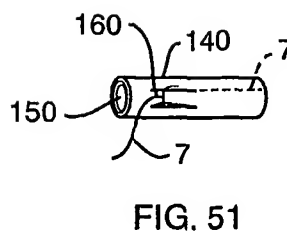
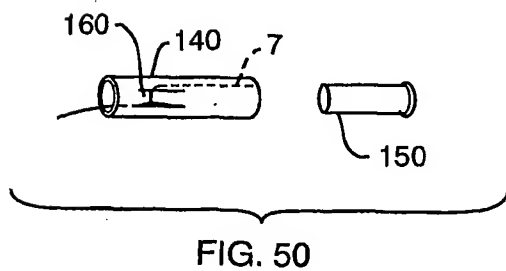
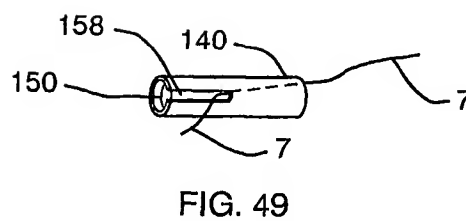
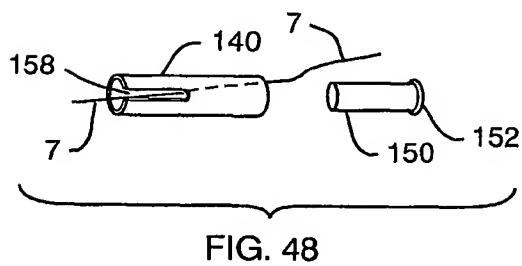
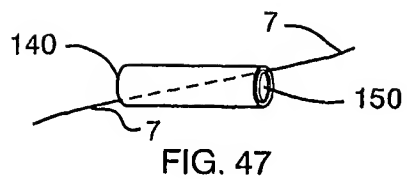
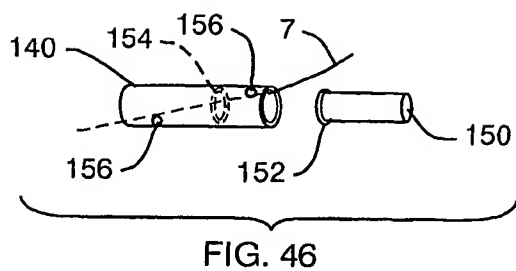


FIG. 45

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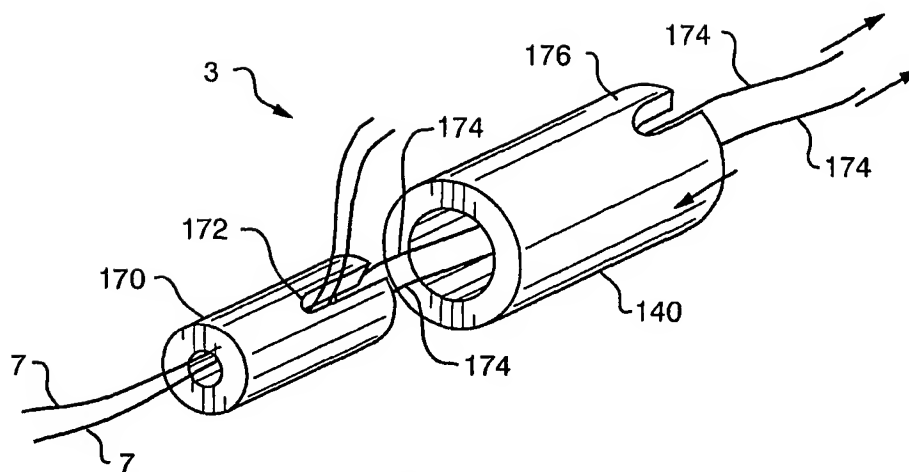


FIG. 52

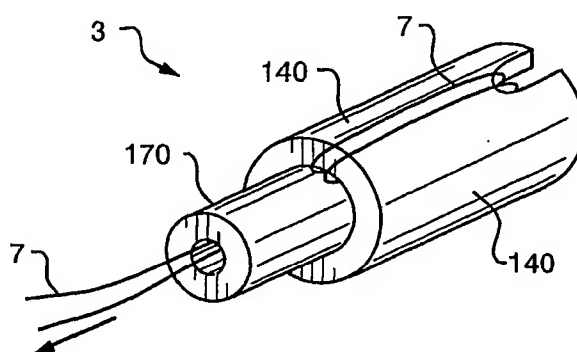
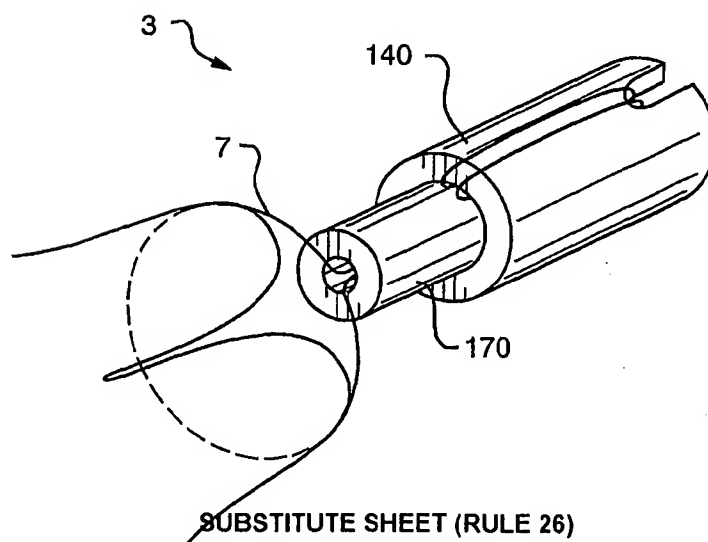


FIG. 53



SUBSTITUTE SHEET (RULE 26)
FIG. 54

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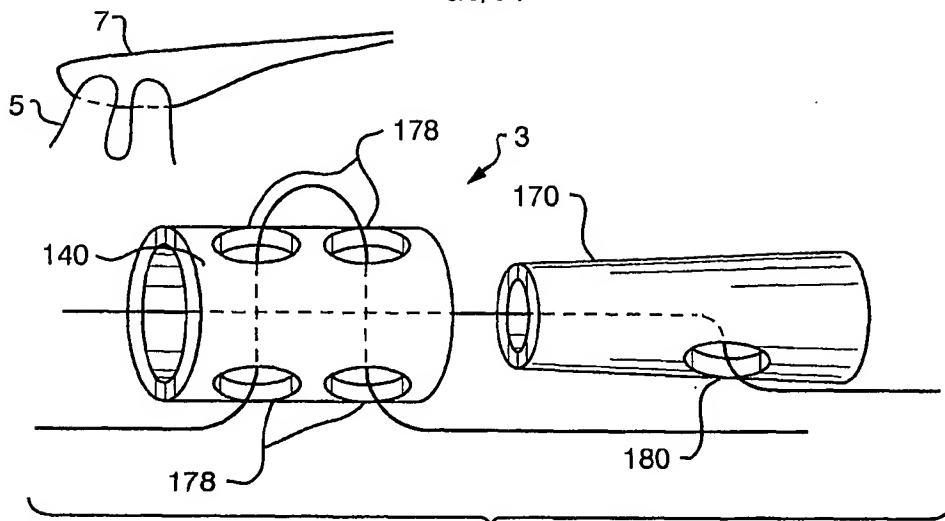


FIG. 55

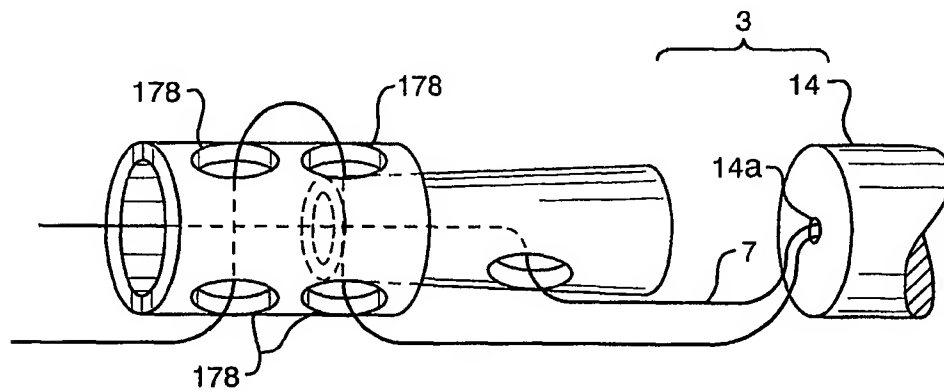
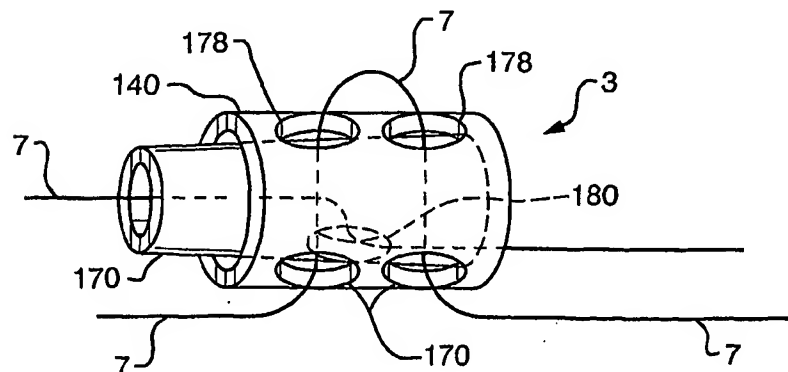


FIG. 56



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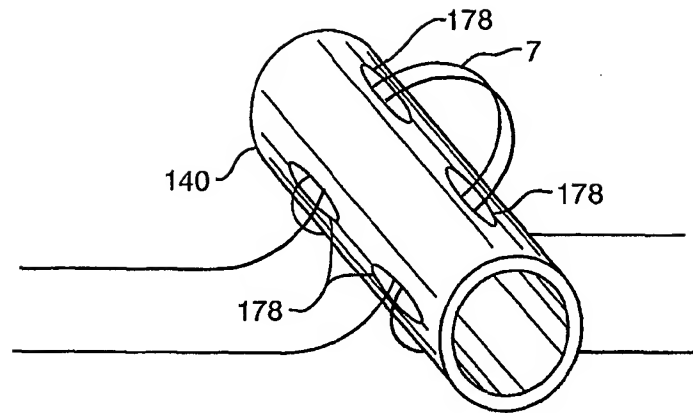


FIG. 58

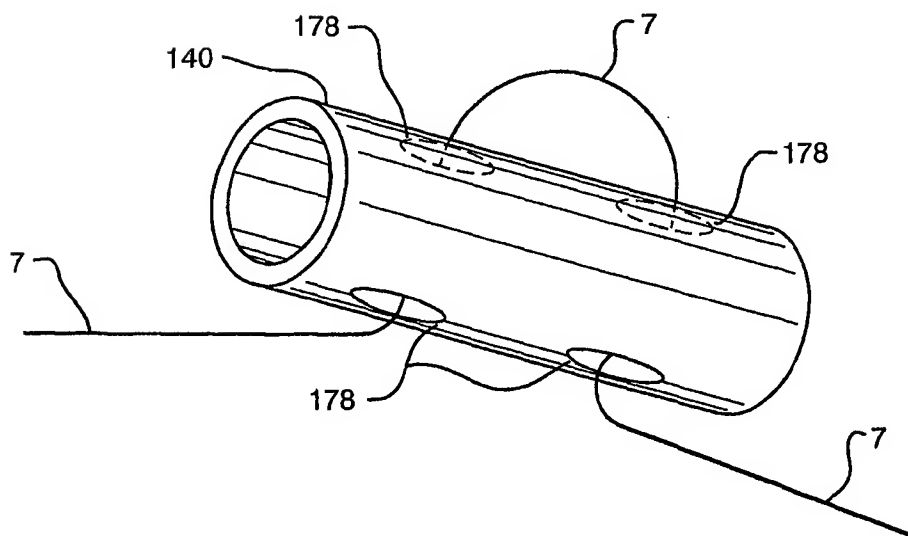


FIG. 59

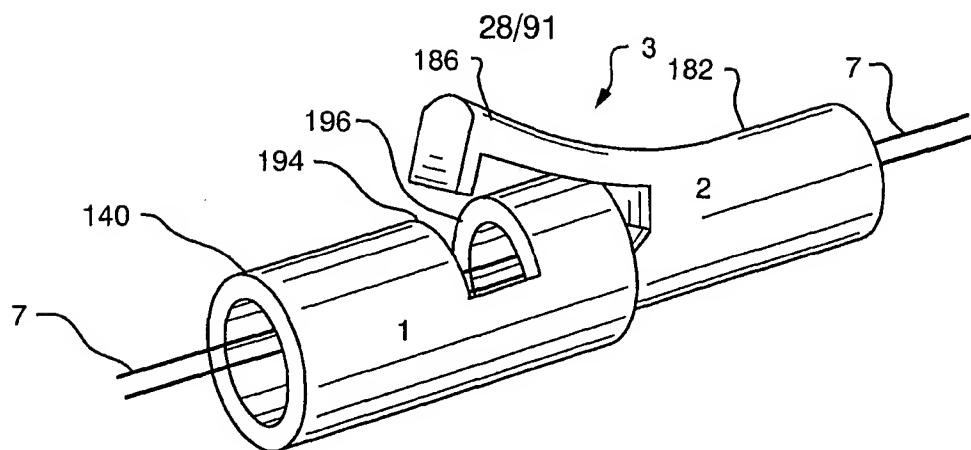


FIG. 60

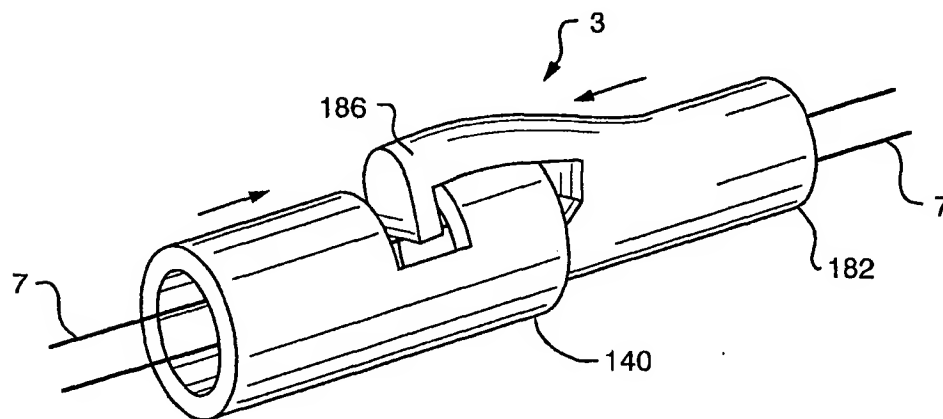


FIG. 61

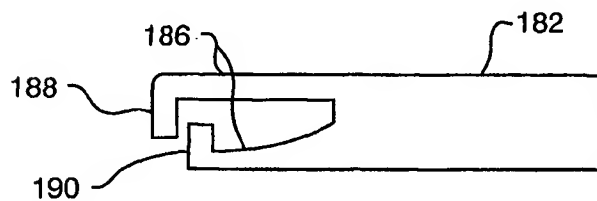
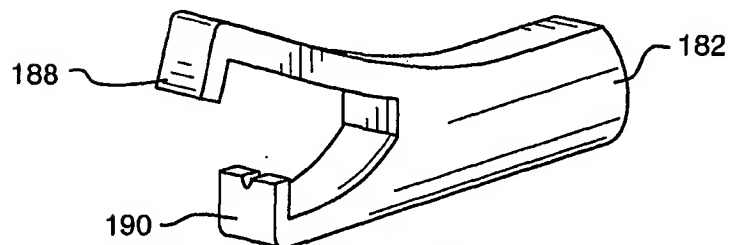


FIG. 62



SUBSTITUTE SHEET (RULE 26)

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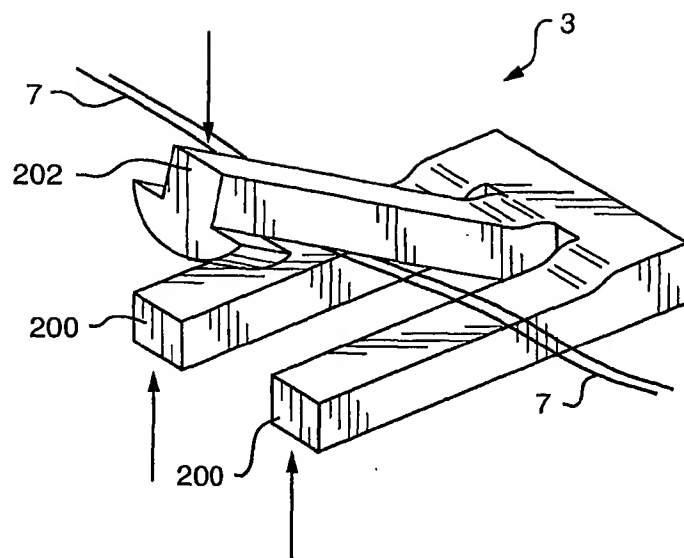


FIG. 64

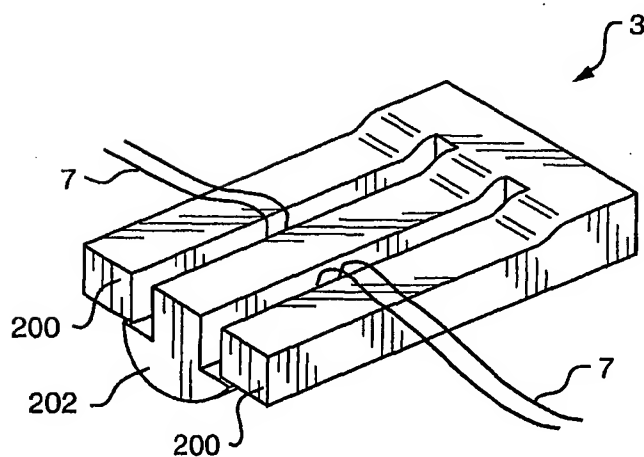


FIG. 65

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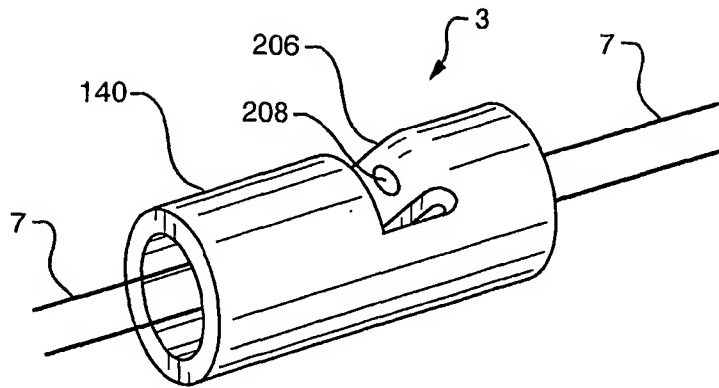


FIG. 66

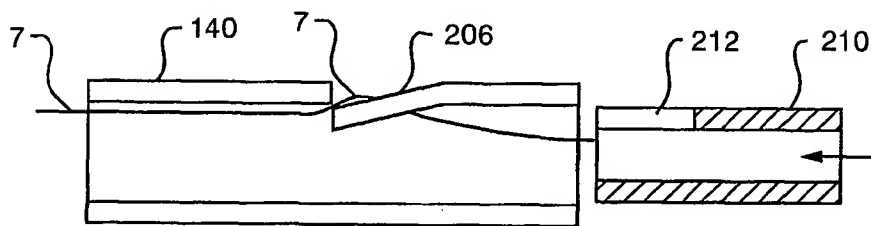


FIG. 67

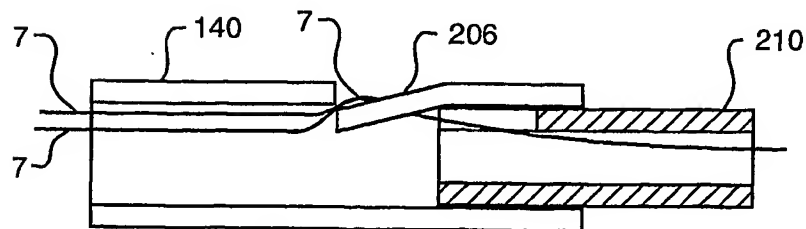


FIG. 68

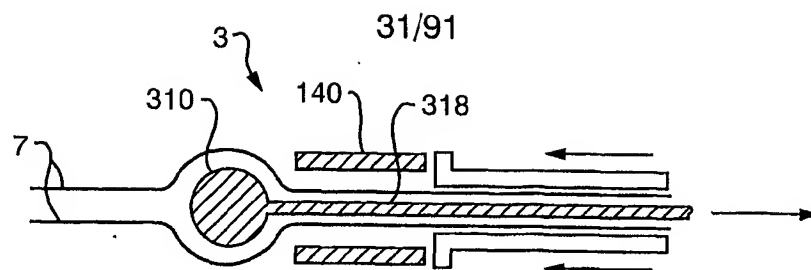


FIG. 69

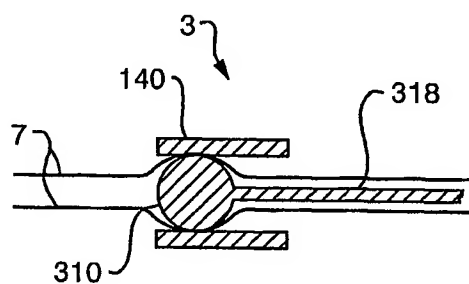


FIG. 70

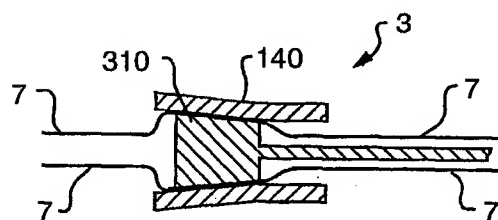


FIG. 71

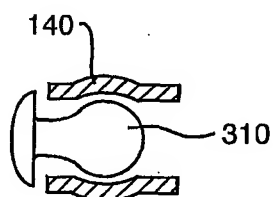


FIG. 72

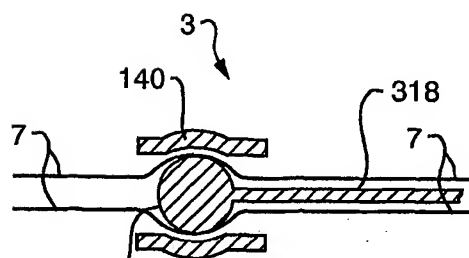


FIG. 73

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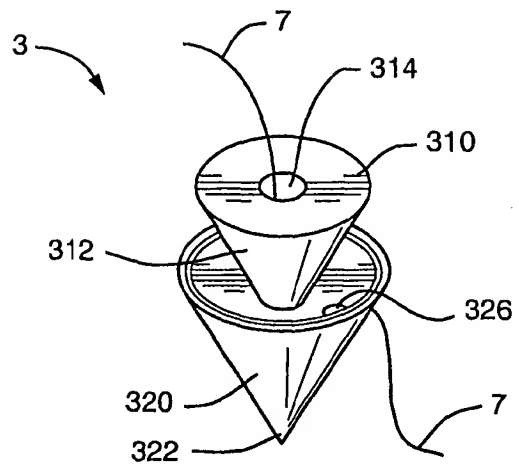


FIG. 74

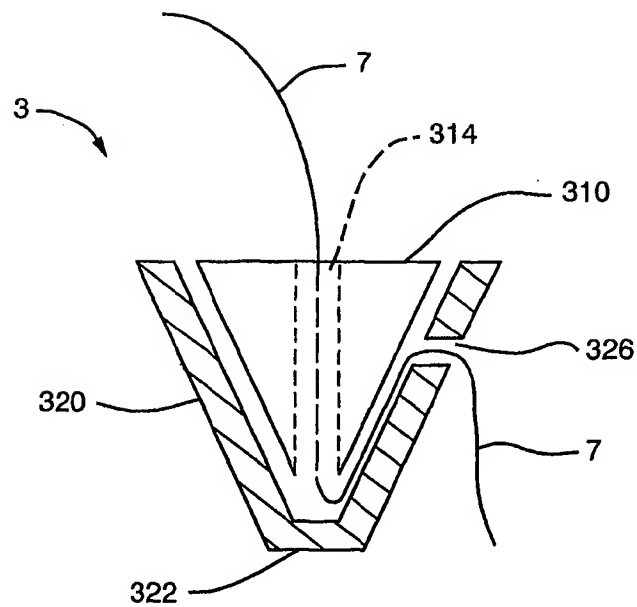
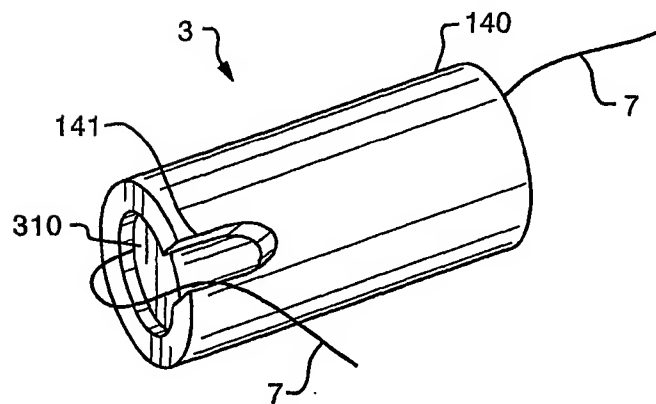
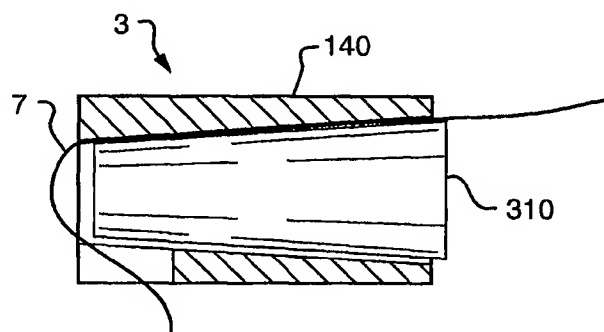
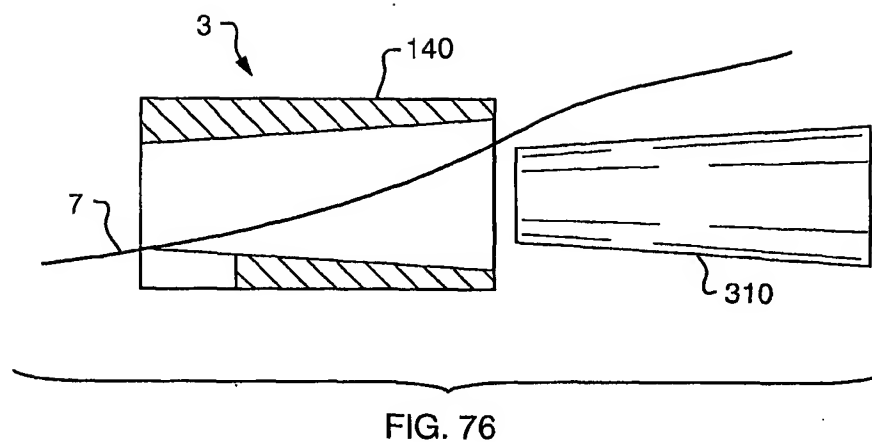


FIG. 75

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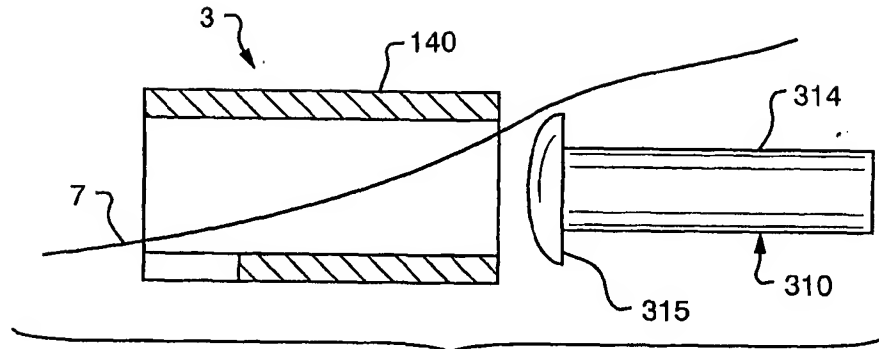


FIG. 79

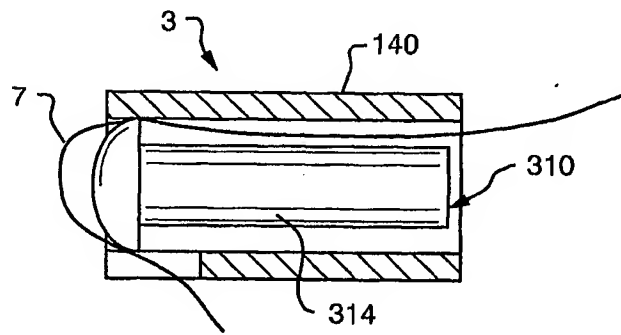


FIG. 80

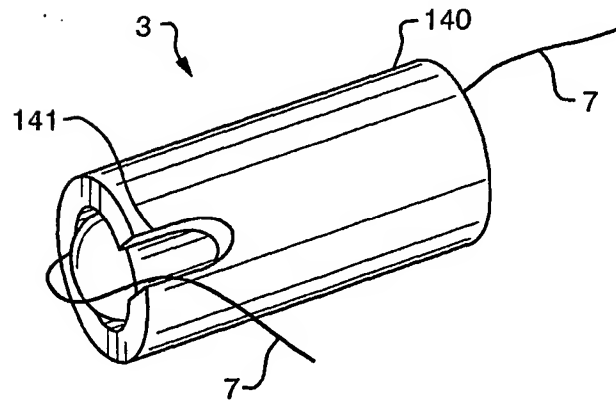


FIG. 81

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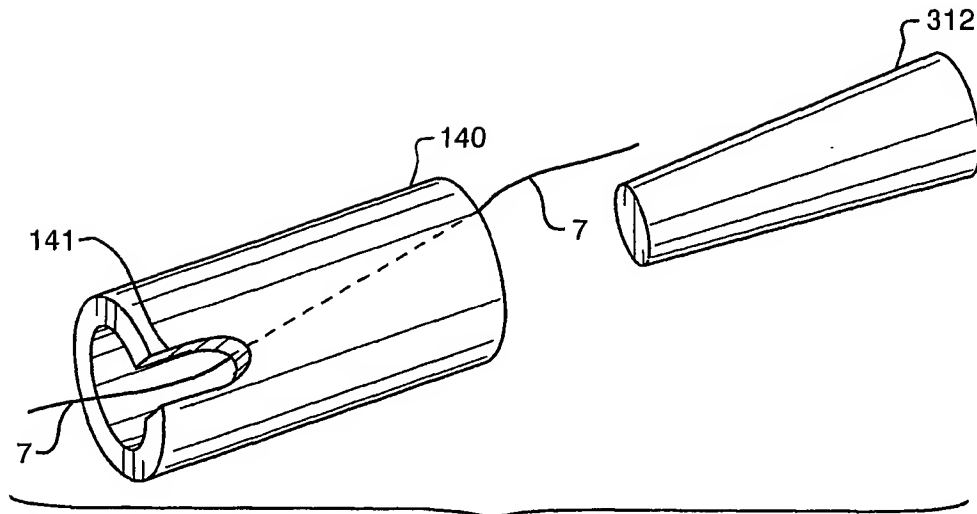


FIG. 82

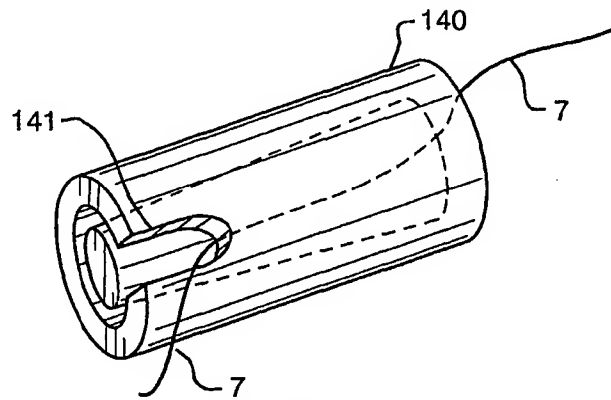


FIG. 83

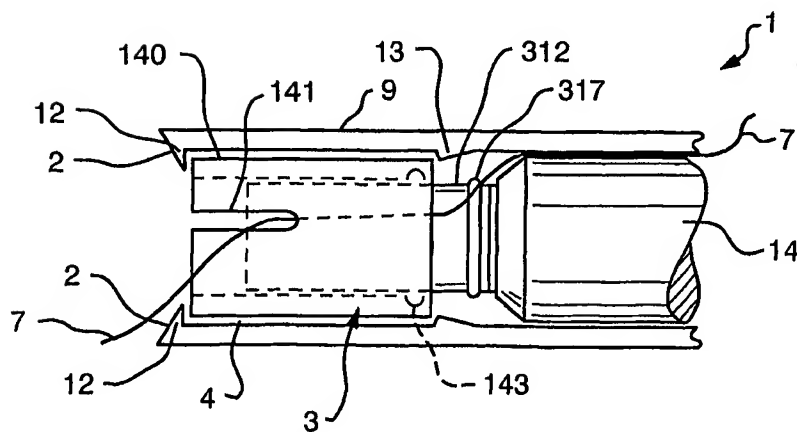


FIG. 84

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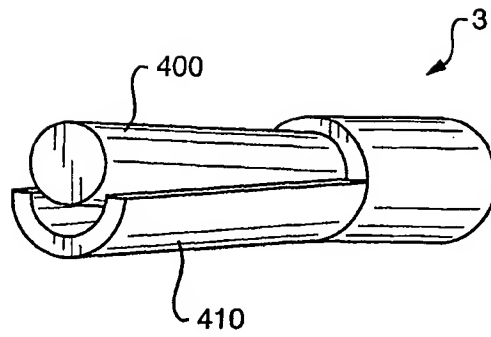


FIG. 91

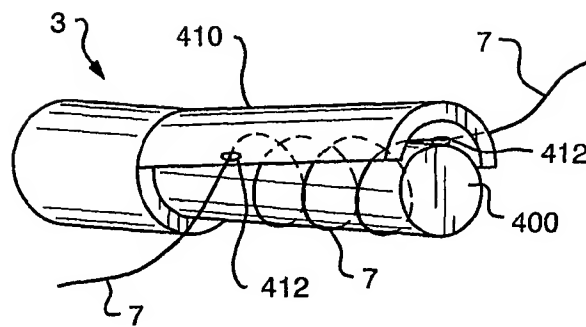


FIG. 93

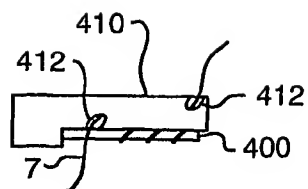


FIG. 94

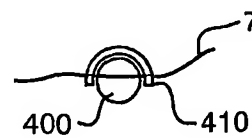


FIG. 95

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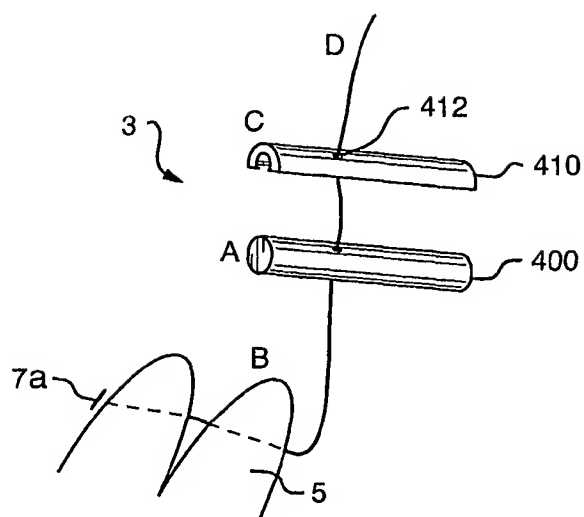


FIG. 96

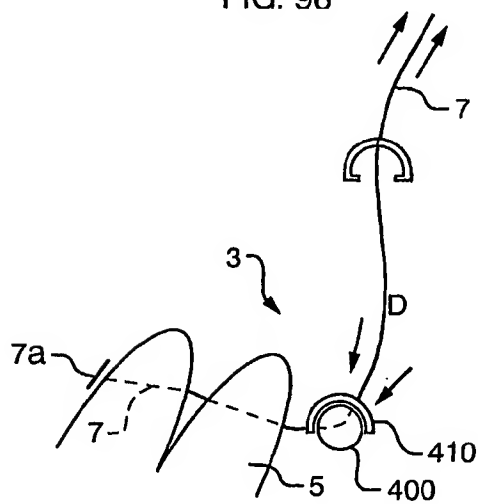


FIG. 97

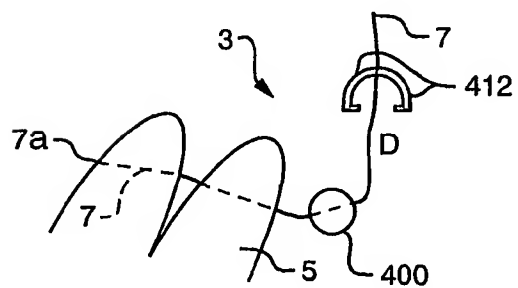


FIG. 98

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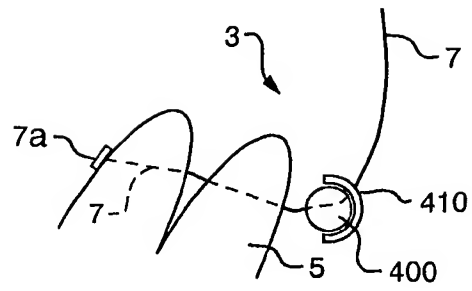


FIG. 99

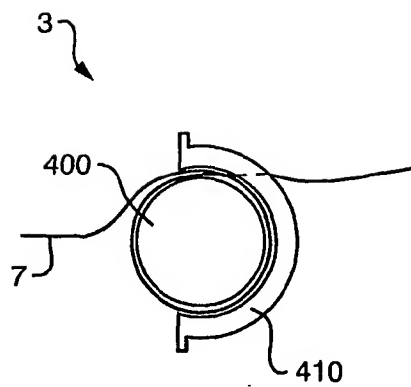


FIG. 100

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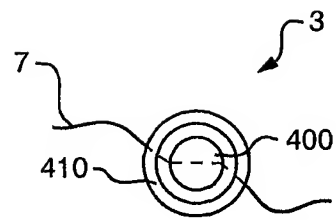


FIG. 101

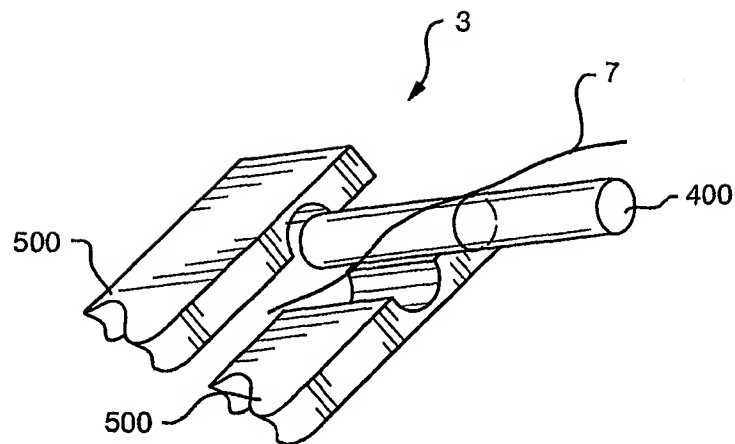


FIG. 102

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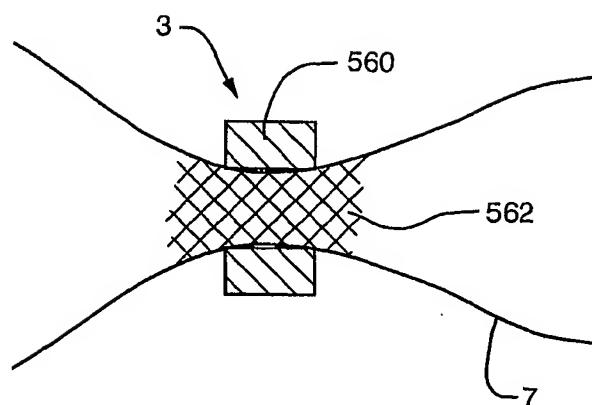


FIG. 103

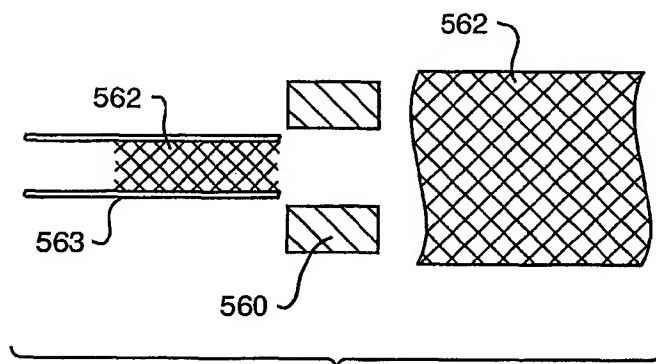


FIG. 104

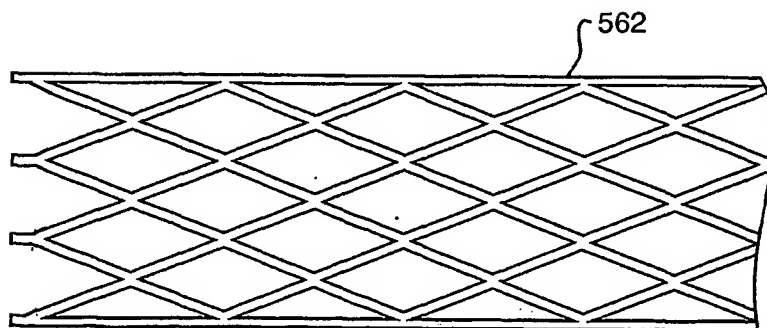
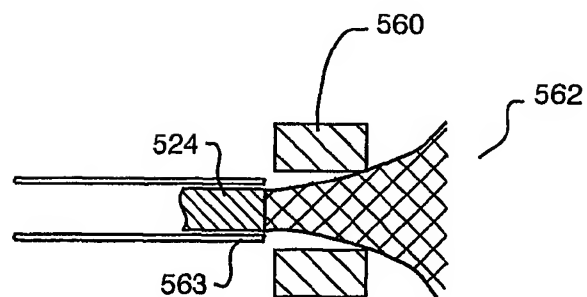
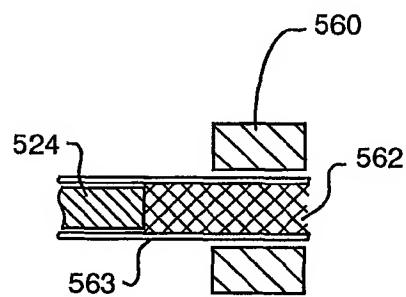
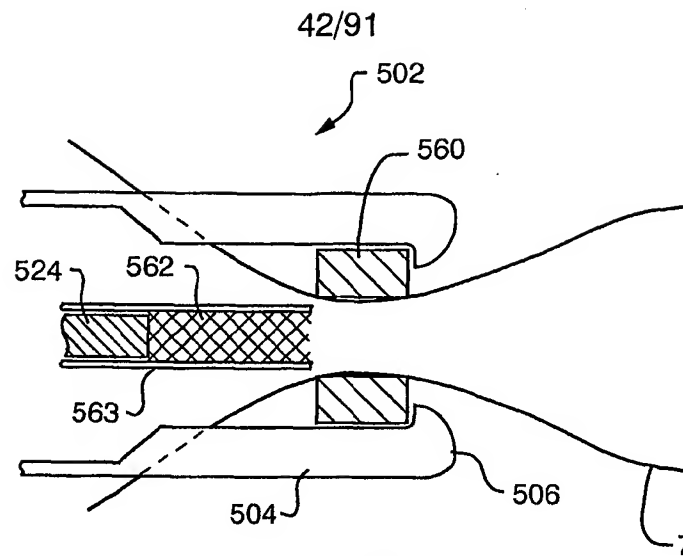


FIG. 105



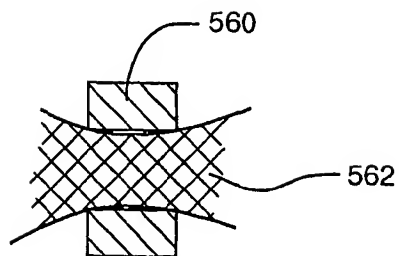


FIG. 109

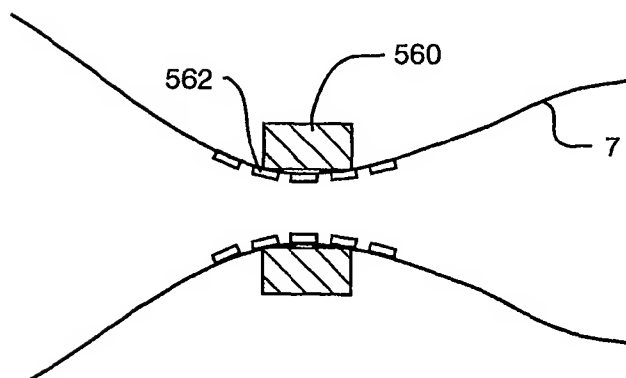


FIG. 110

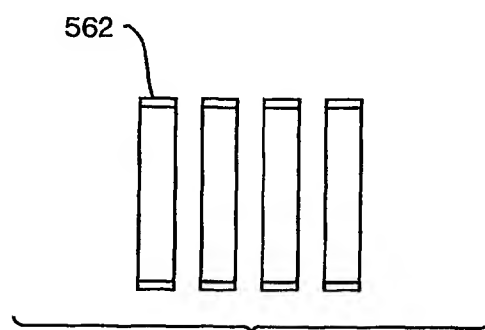


FIG. 111

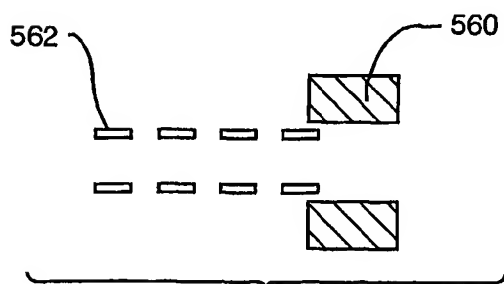


FIG. 112

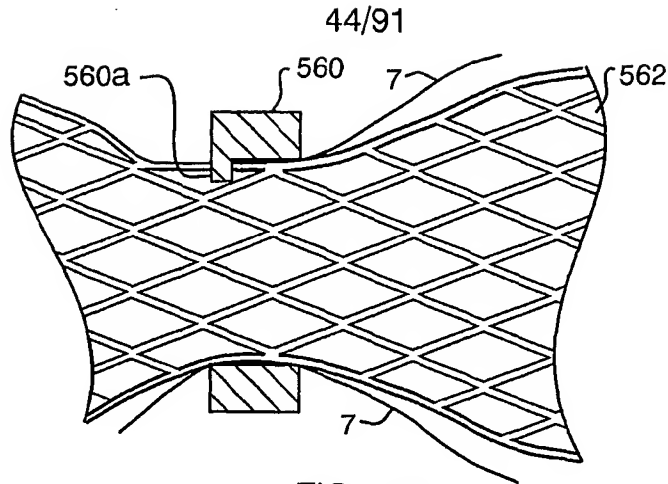


FIG. 113

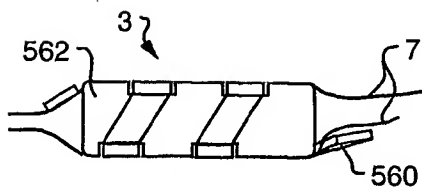


FIG. 114

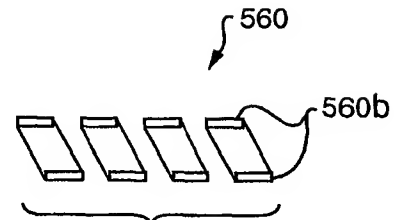


FIG. 115

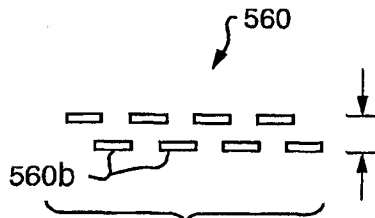


FIG. 116

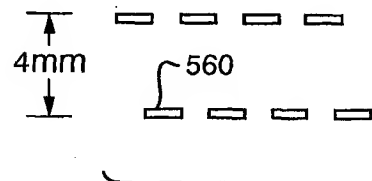


FIG. 117

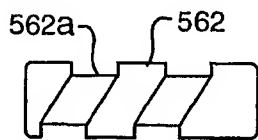


FIG. 118

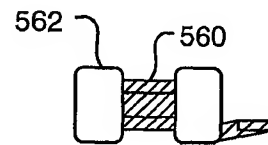


FIG. 120

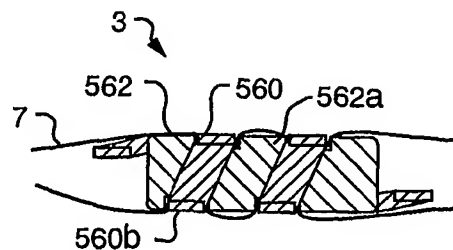


FIG. 119
SUBSTITUTE SHEET (RULE 26)

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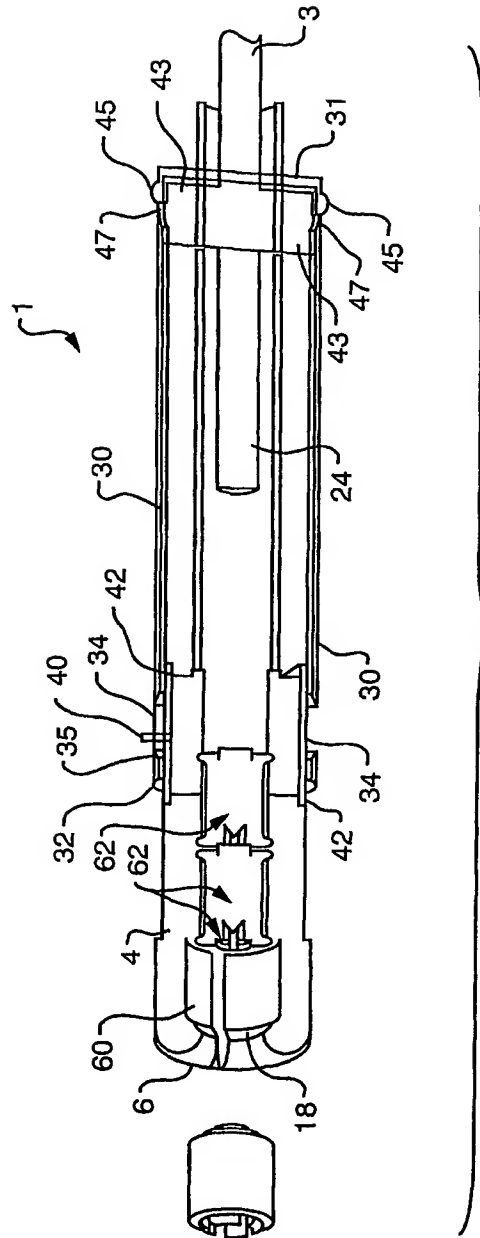
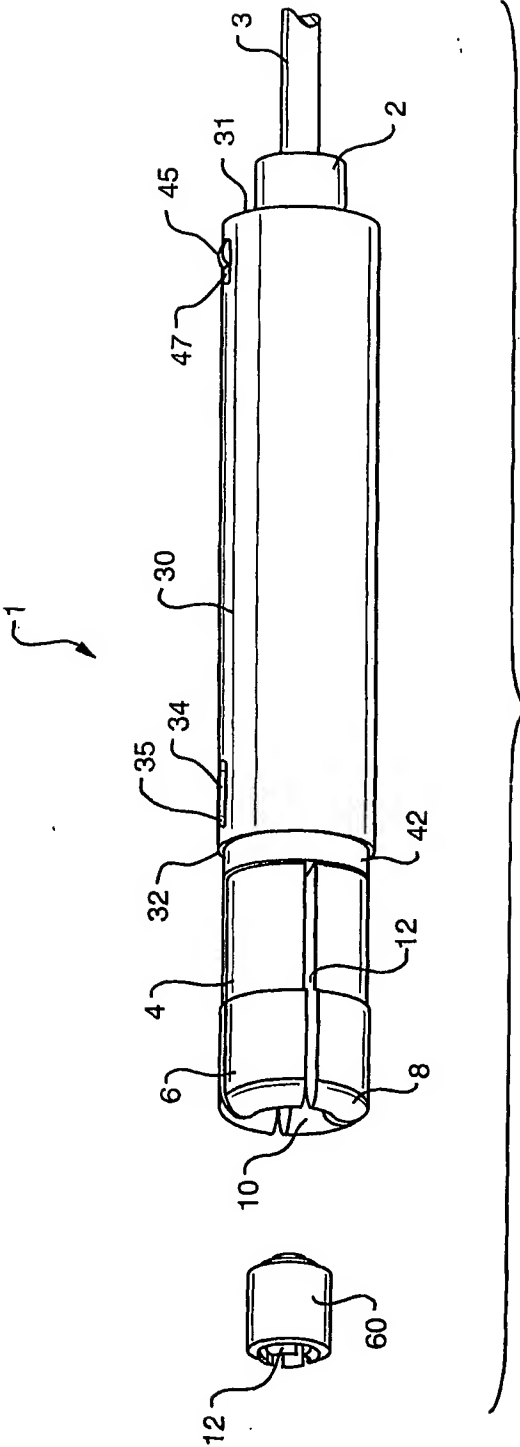


FIG. 121

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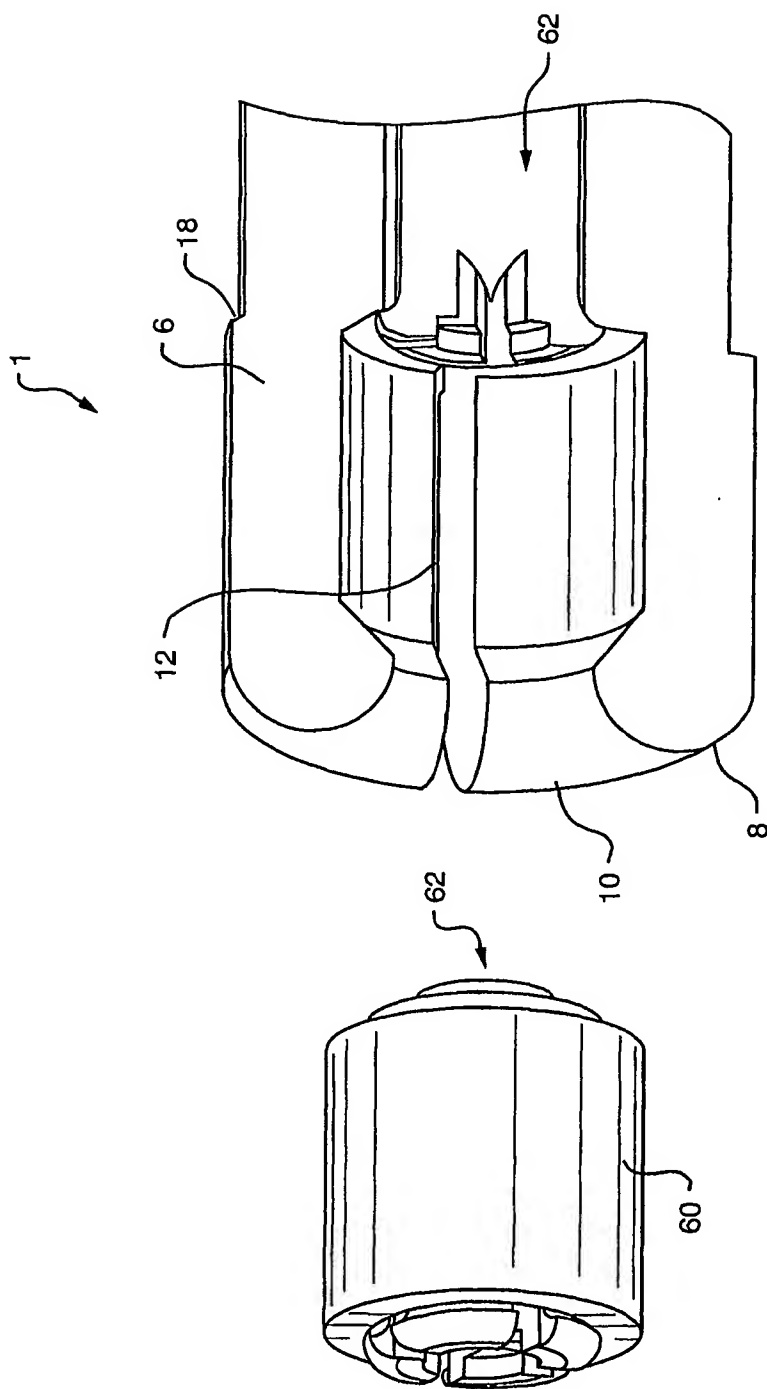


FIG. 123

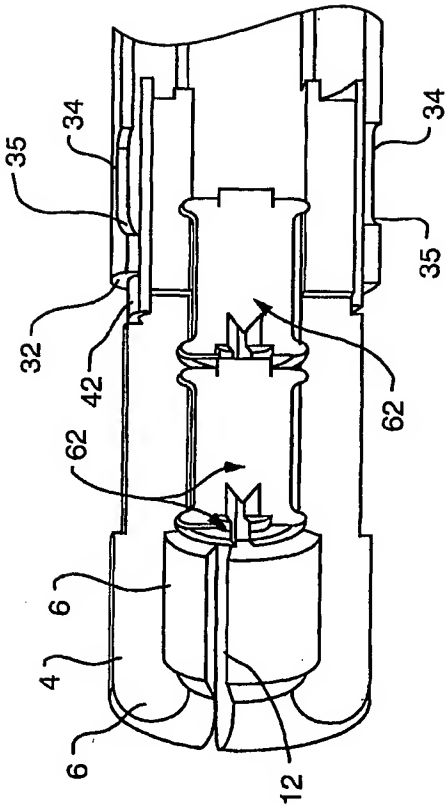


FIG. 124

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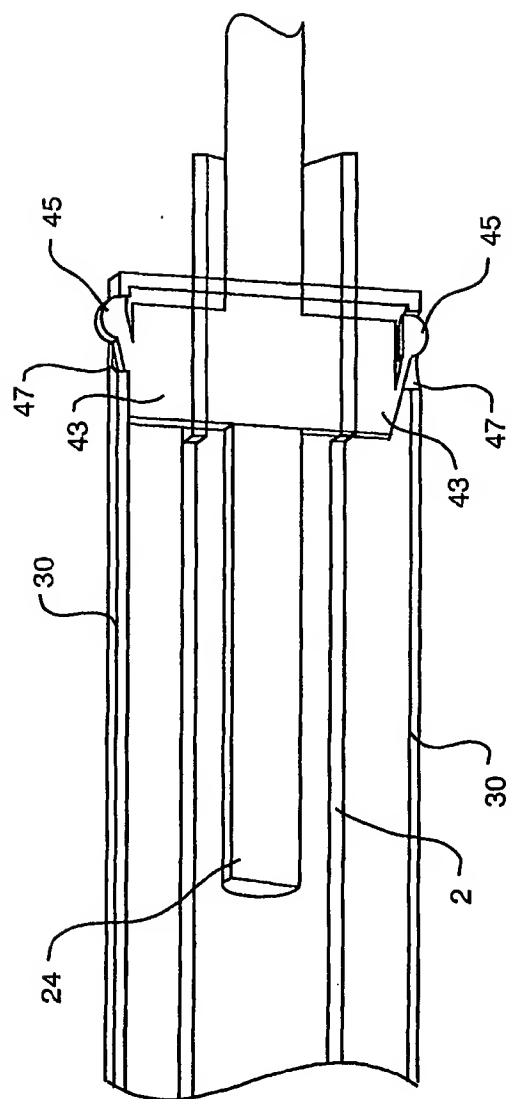


FIG. 125

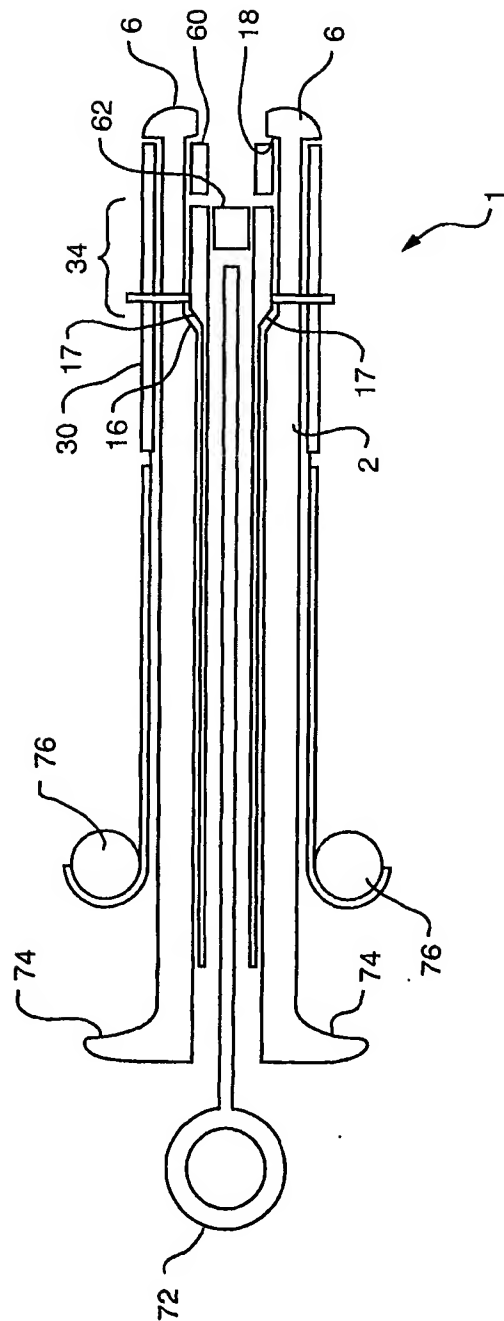


FIG. 126

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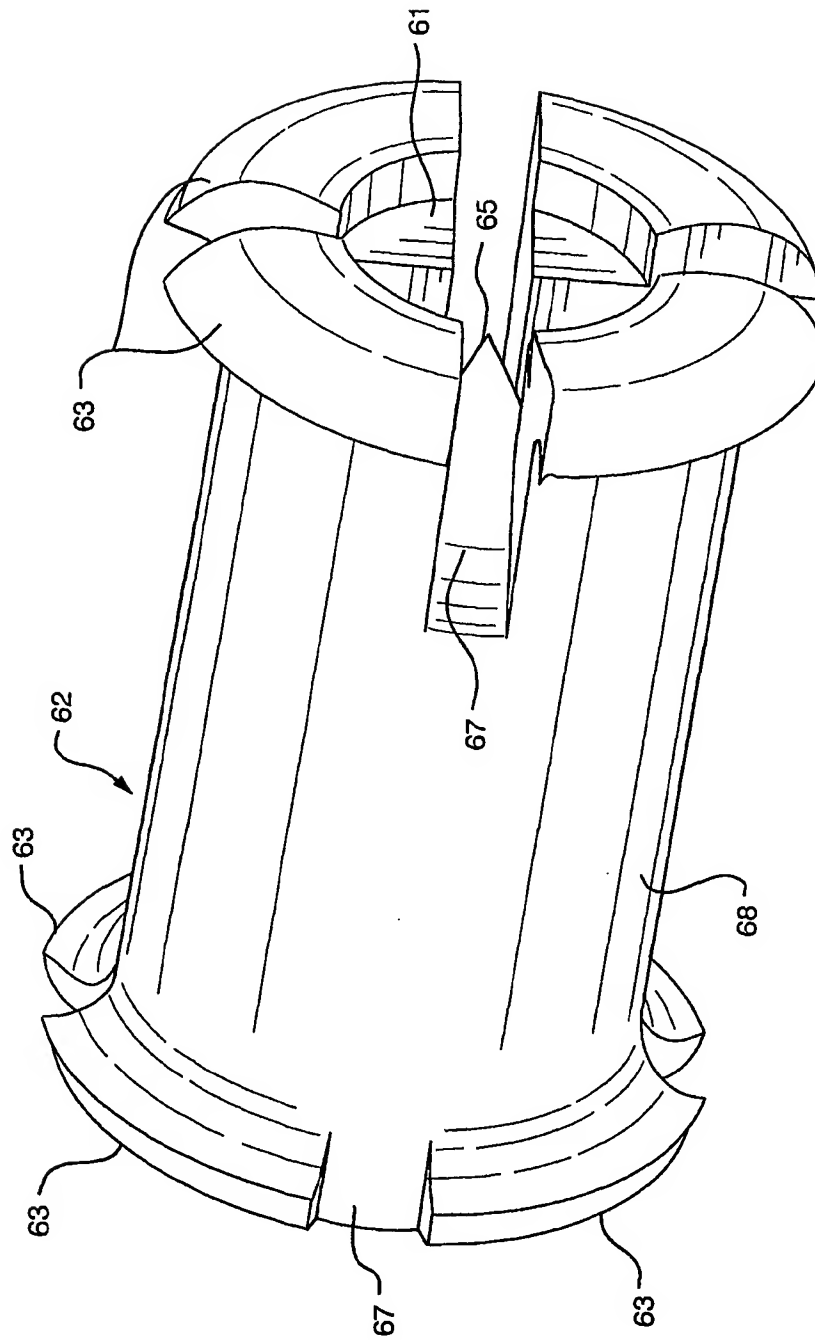
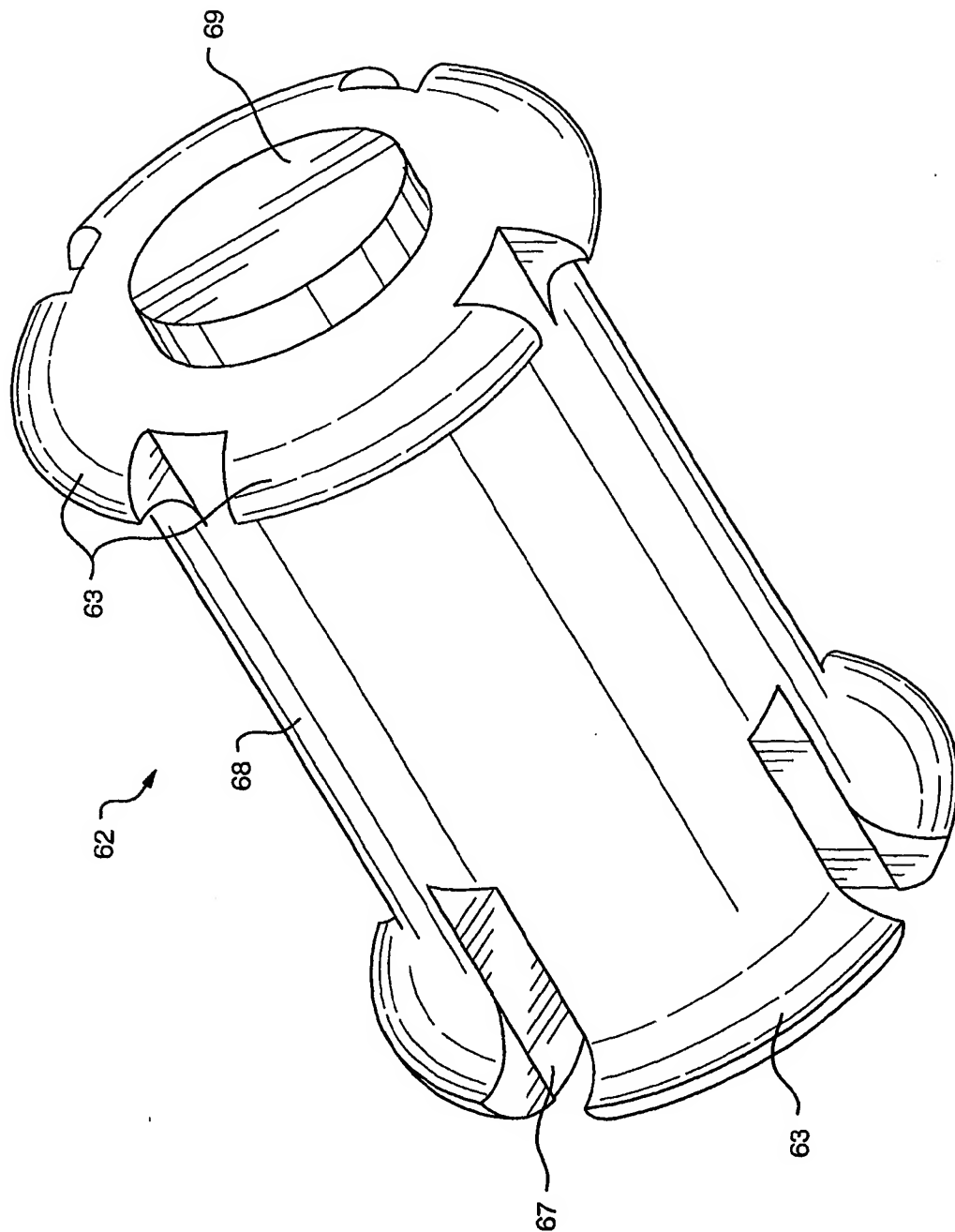


FIG. 127

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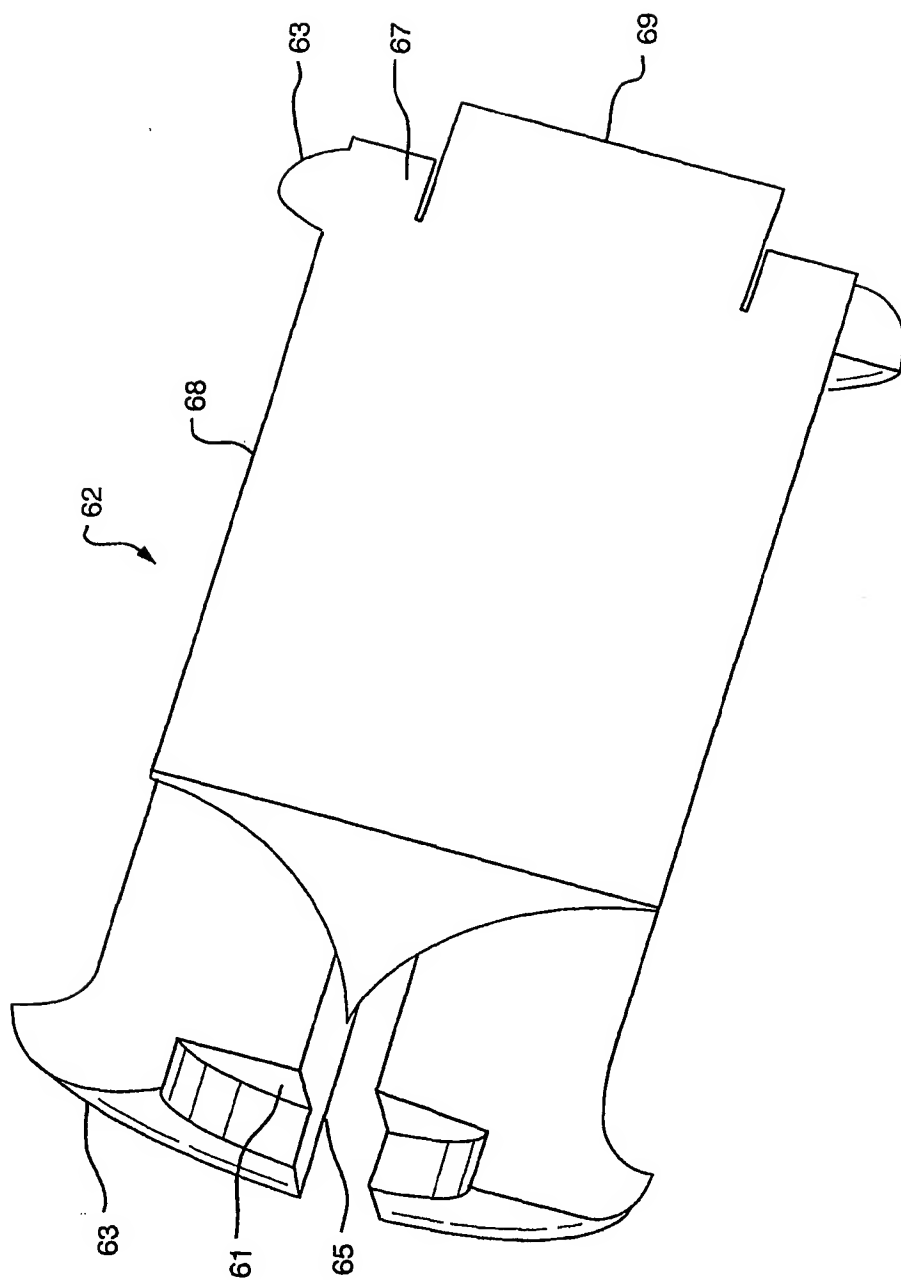


FIG. 129

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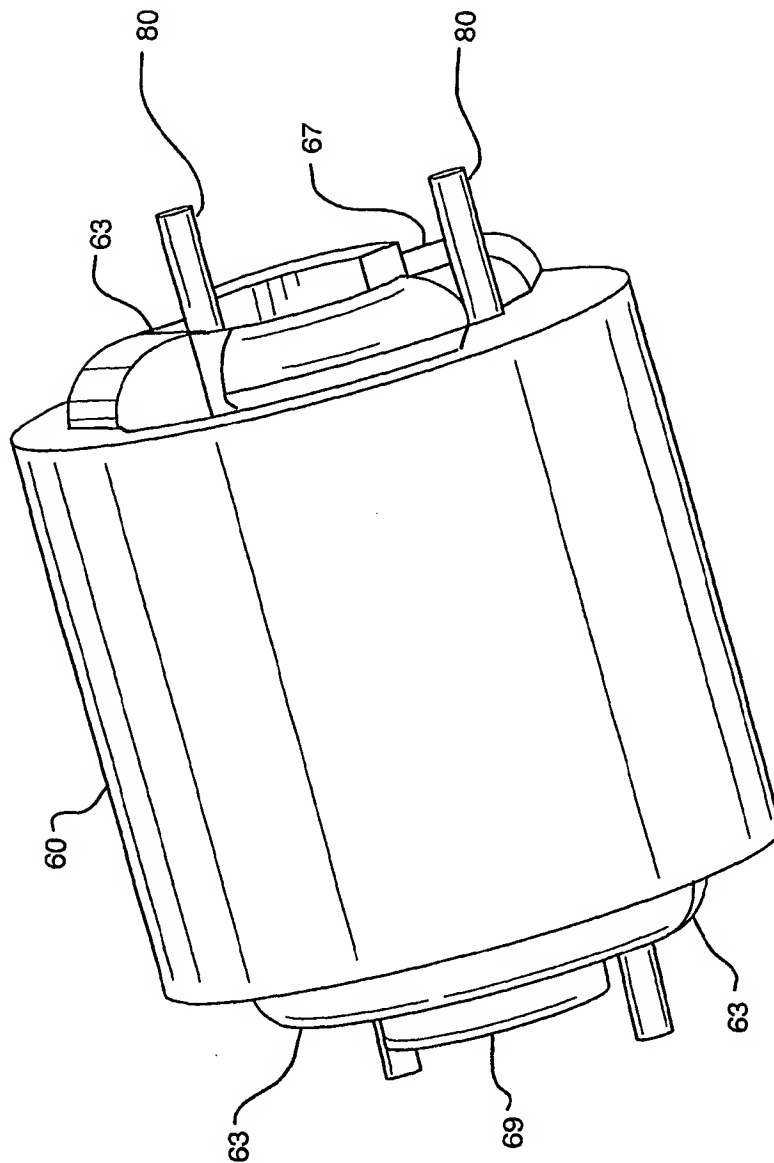


FIG. 130

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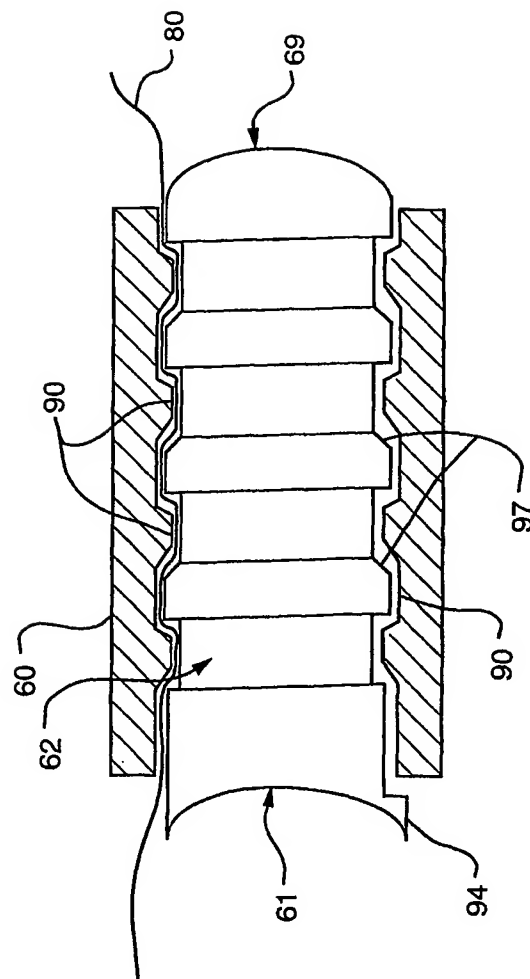


FIG. 131

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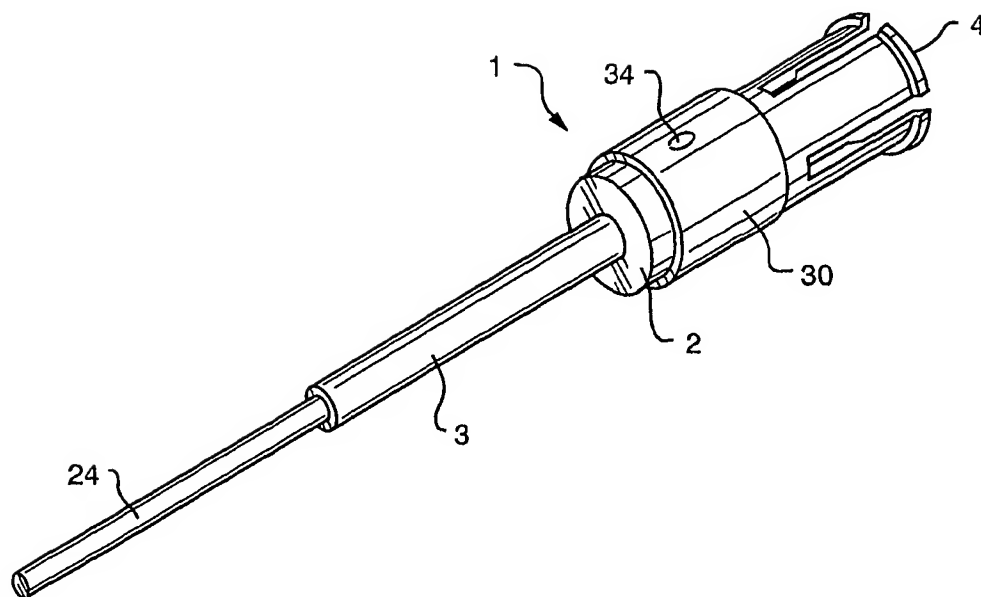
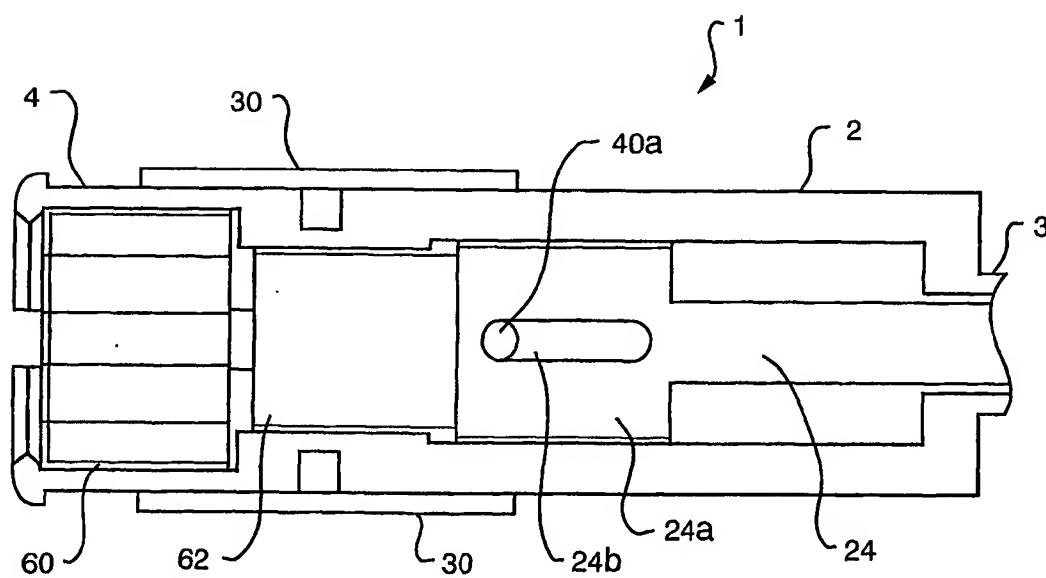


FIG. 132



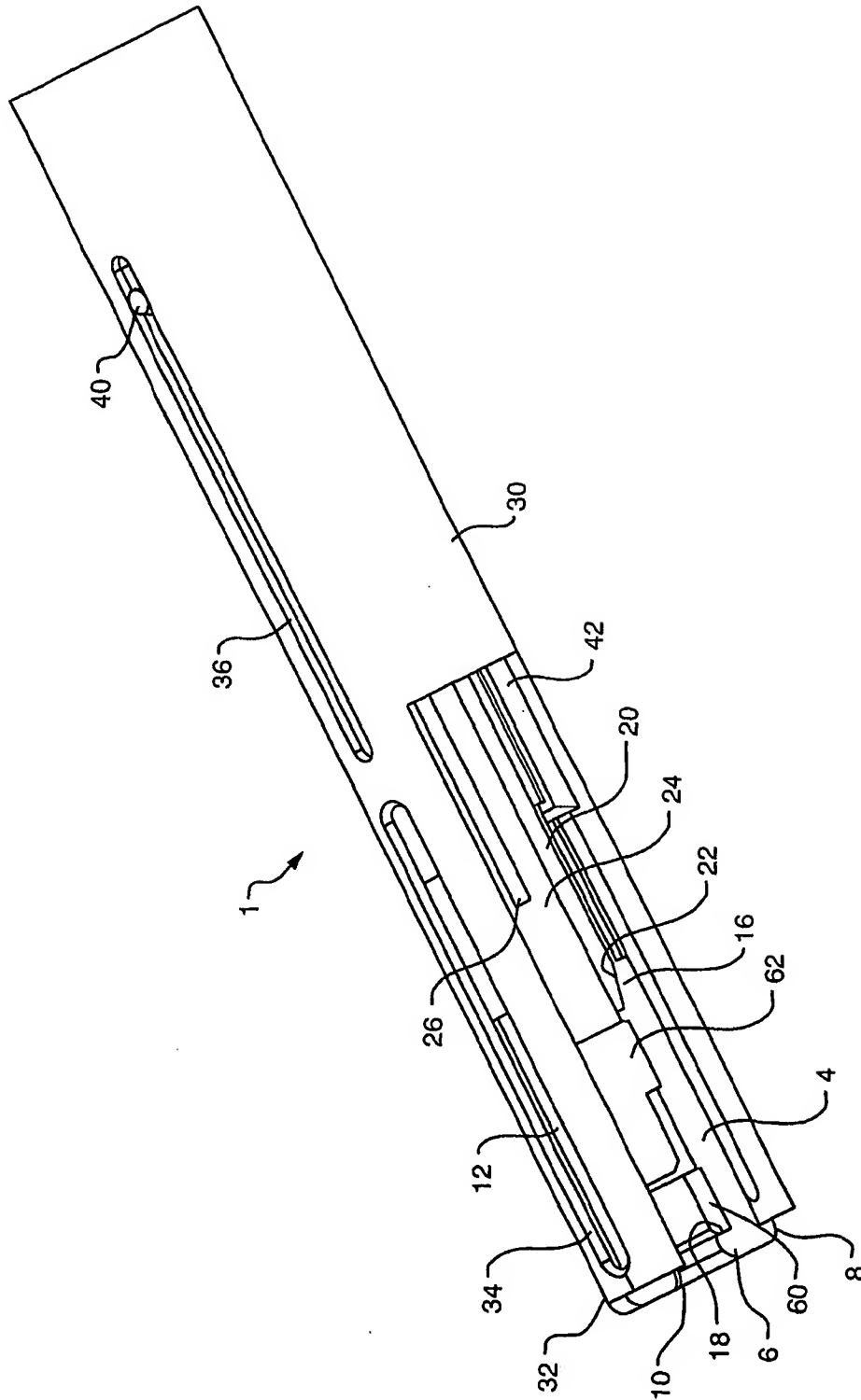


FIG. 134

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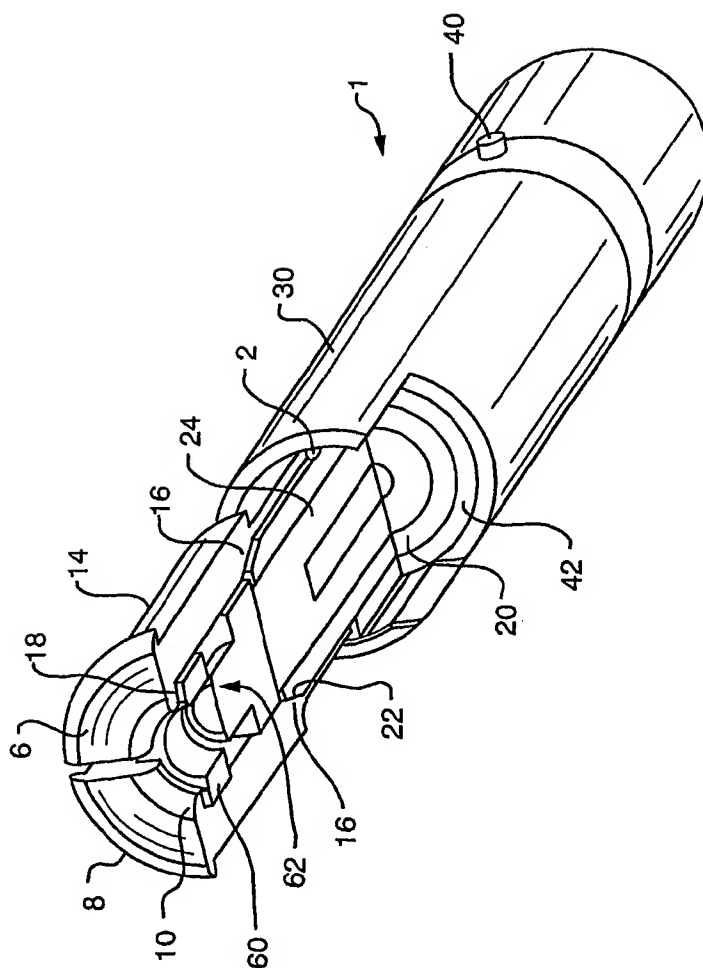


FIG. 135

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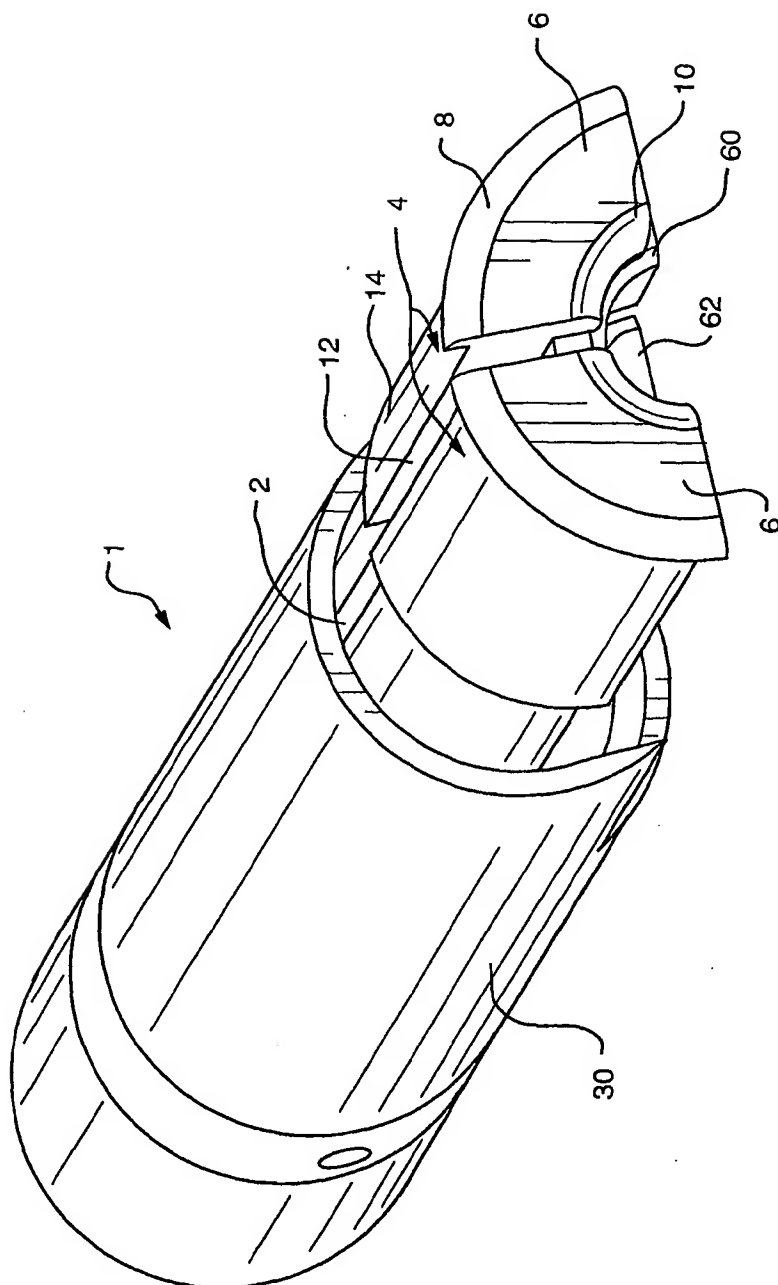


FIG. 136

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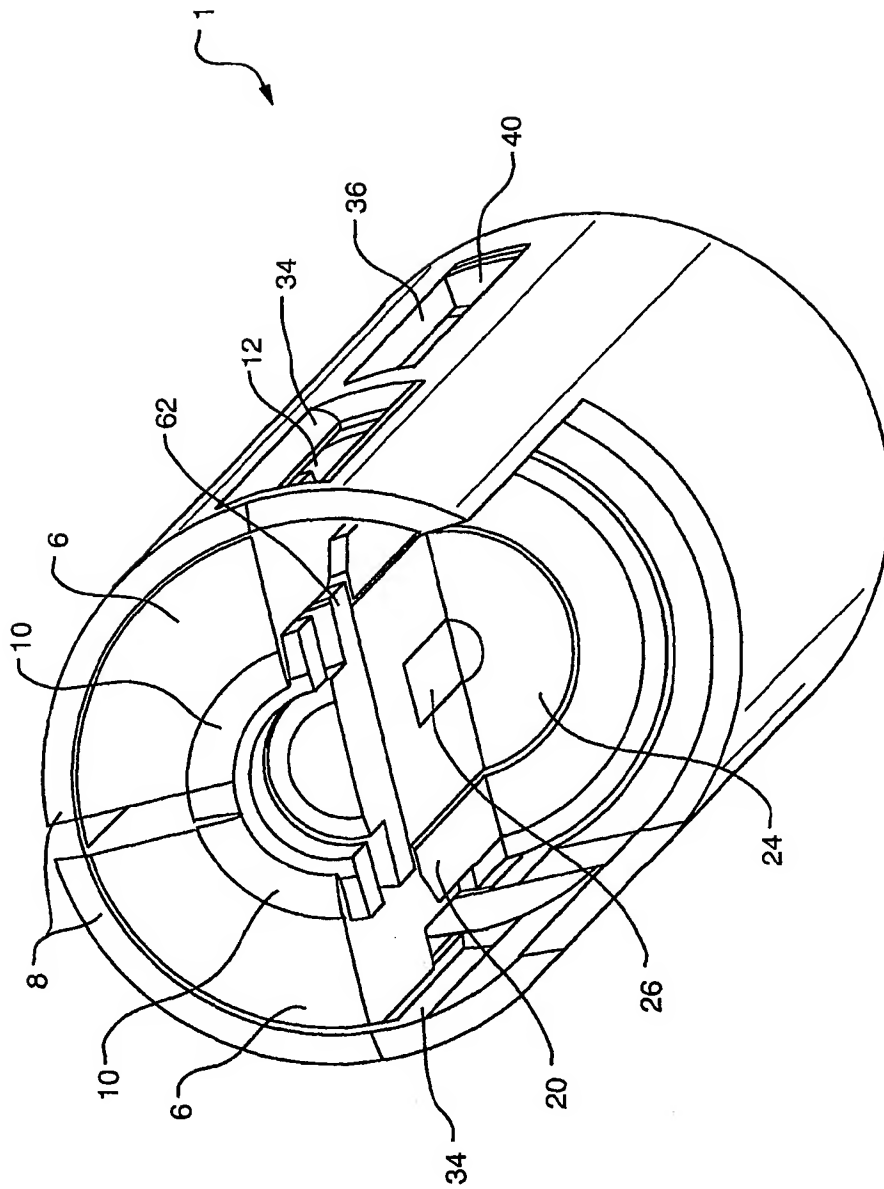


FIG. 137

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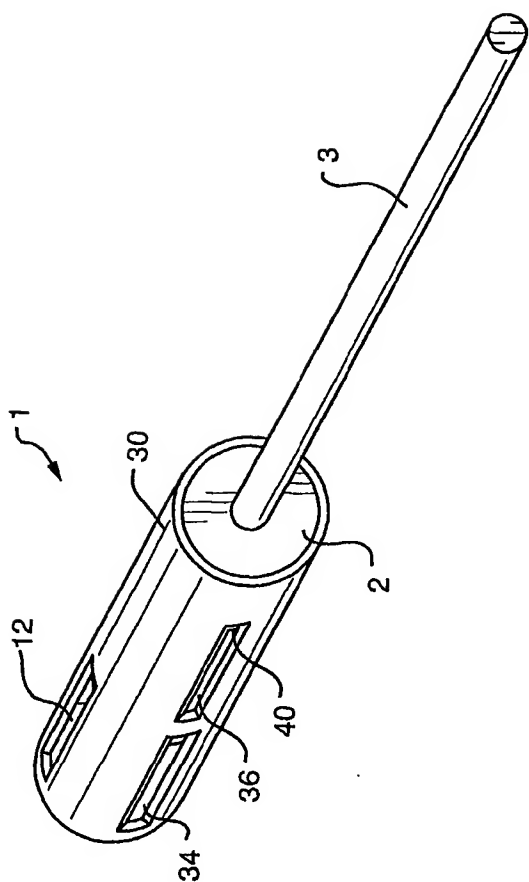


FIG. 138

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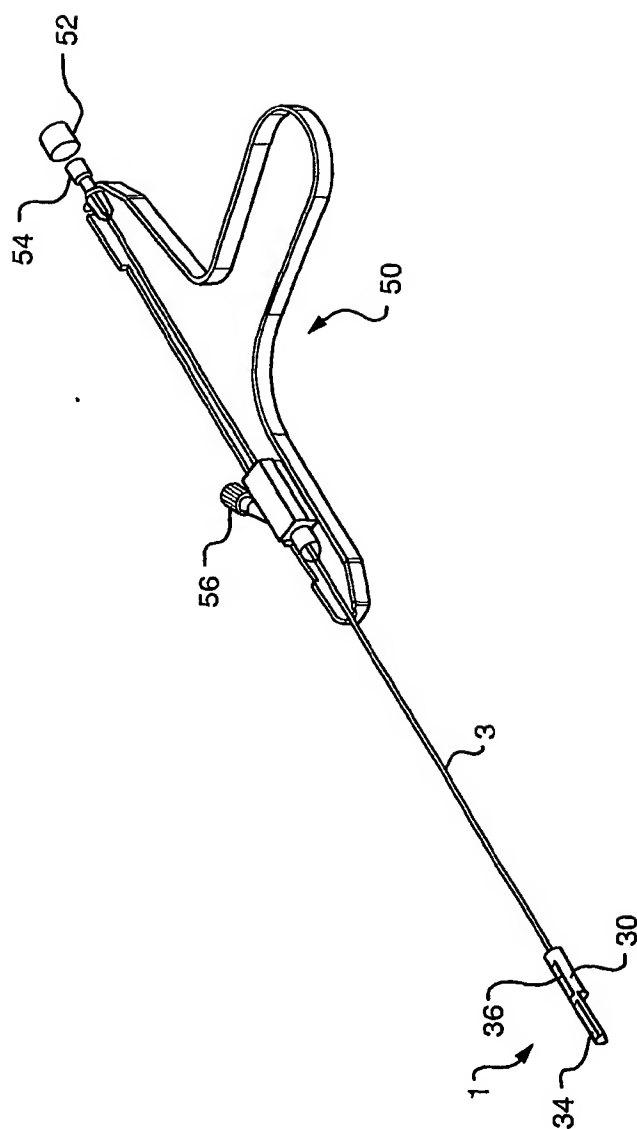


FIG. 139

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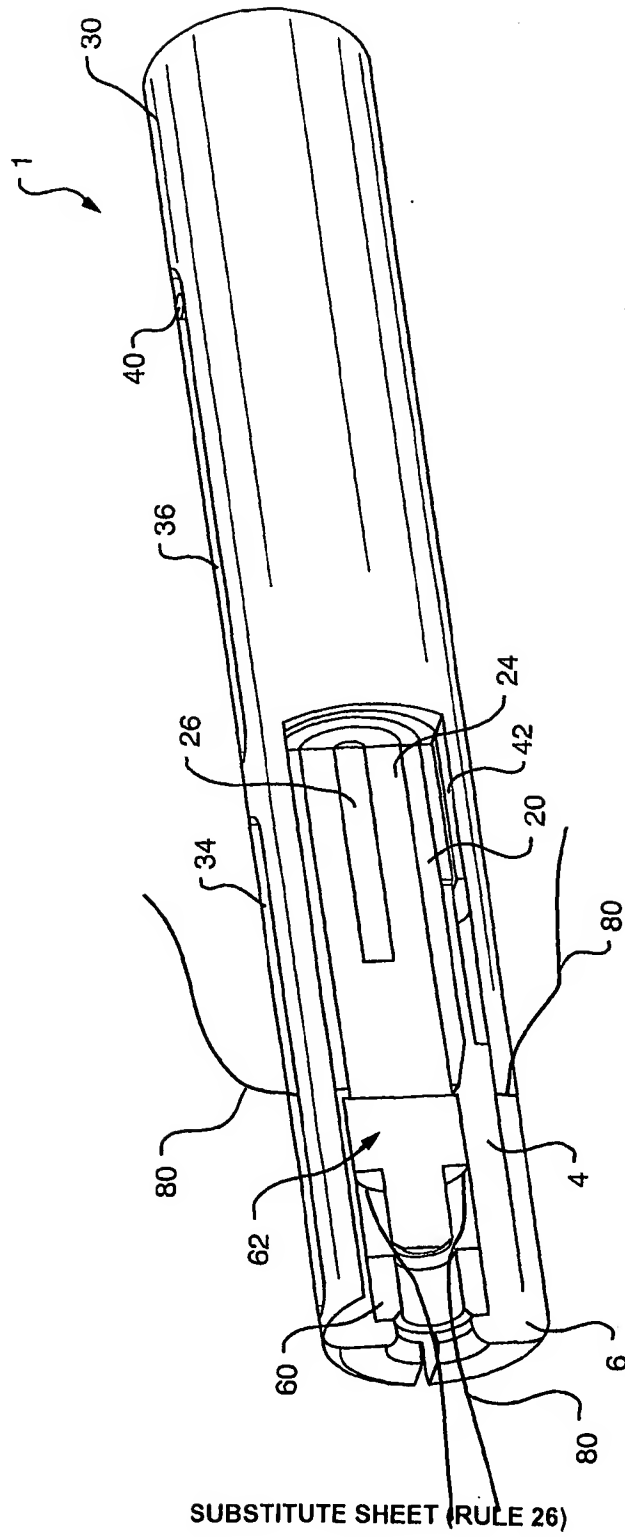


FIG. 140

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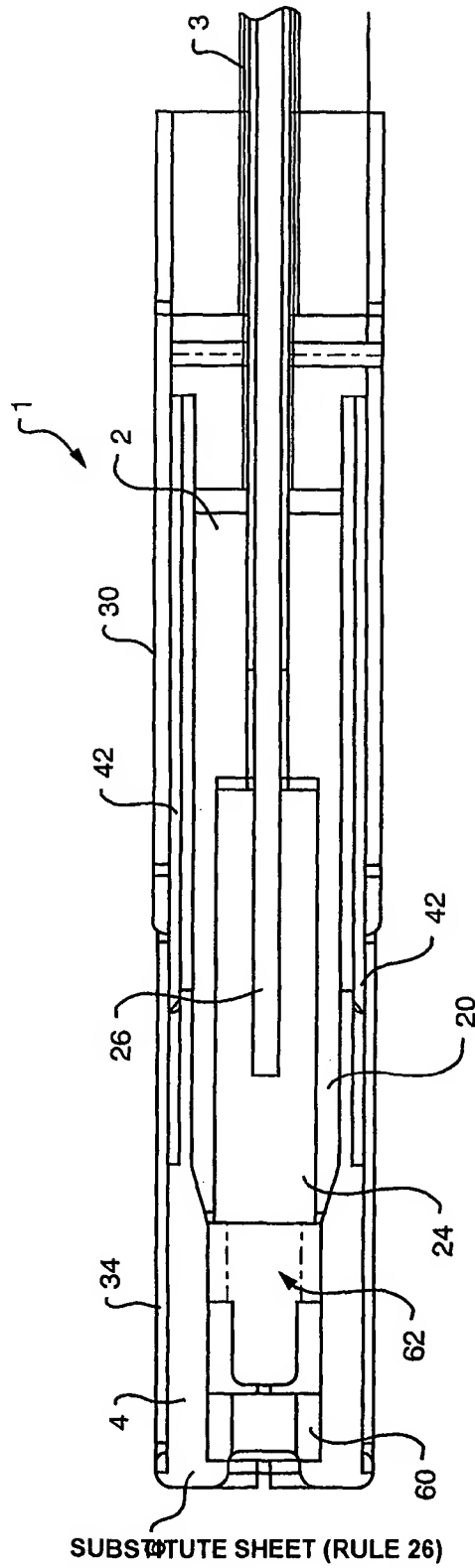


FIG. 141

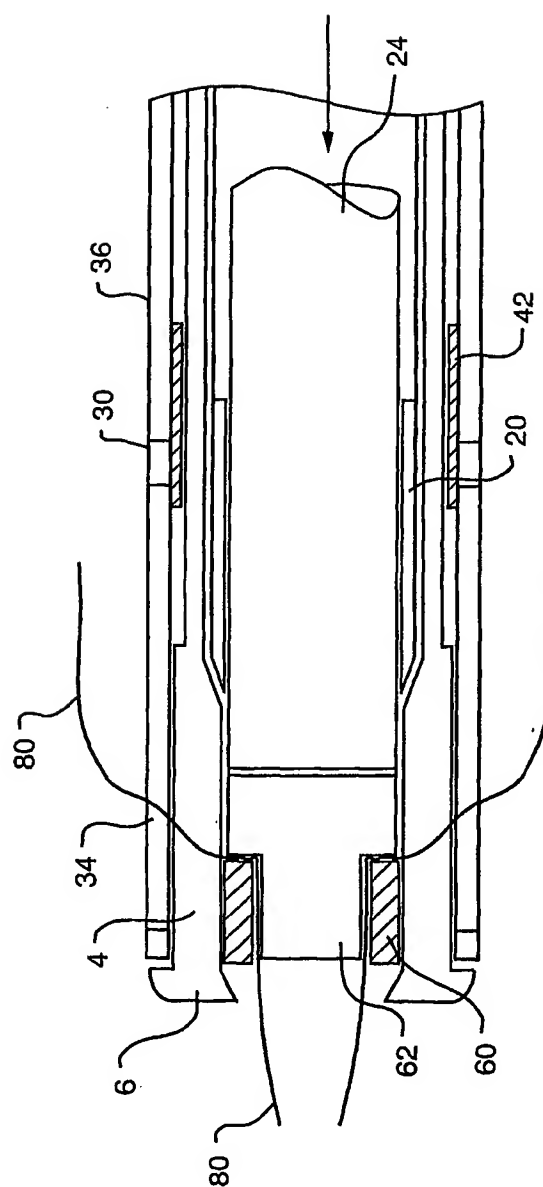


FIG. 142

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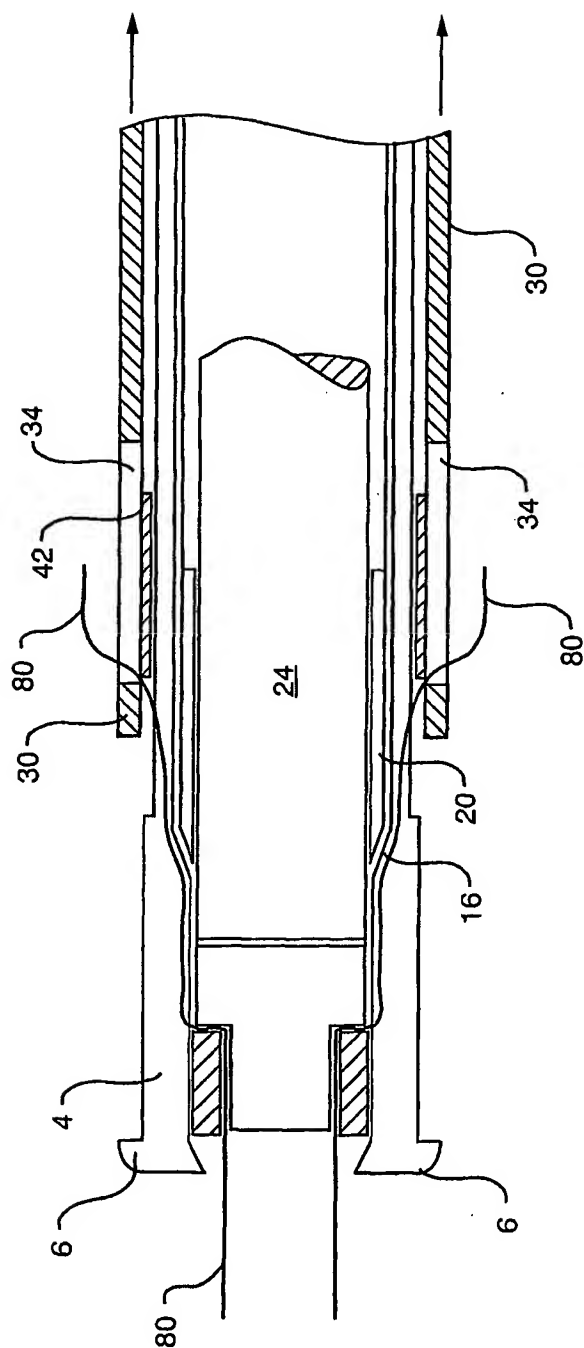


FIG. 143

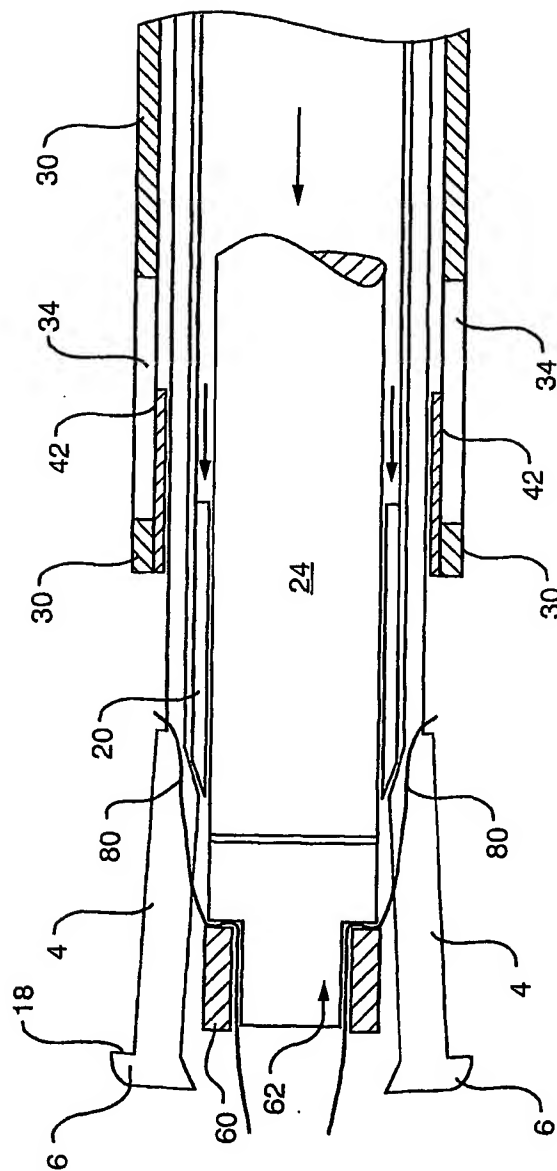


FIG. 145

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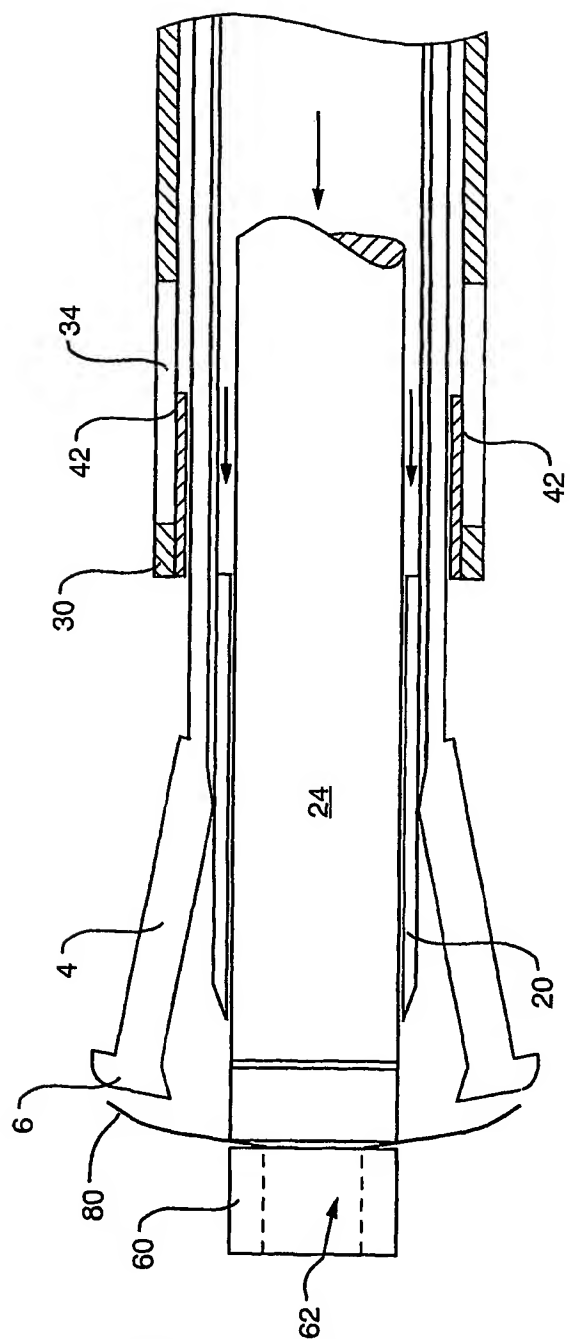


FIG. 146

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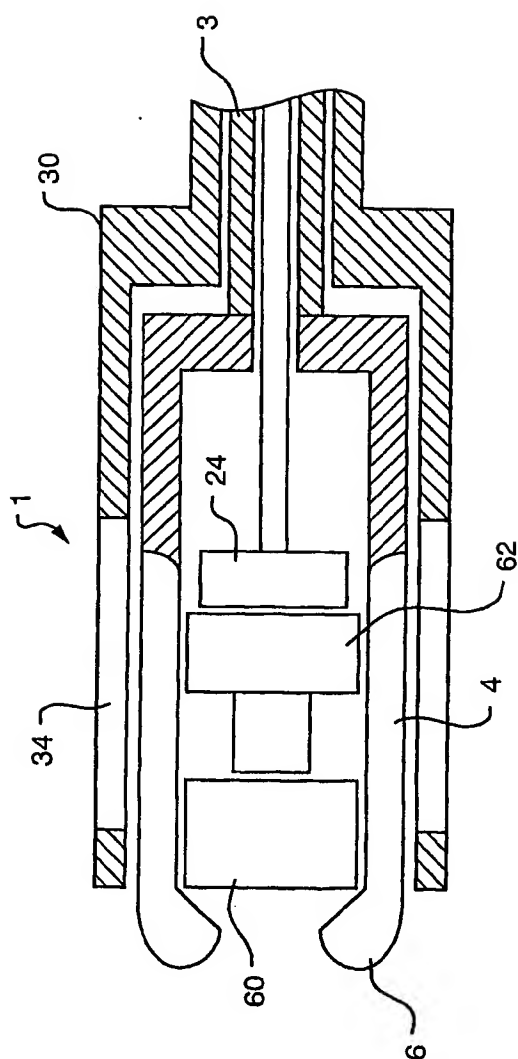


FIG. 147

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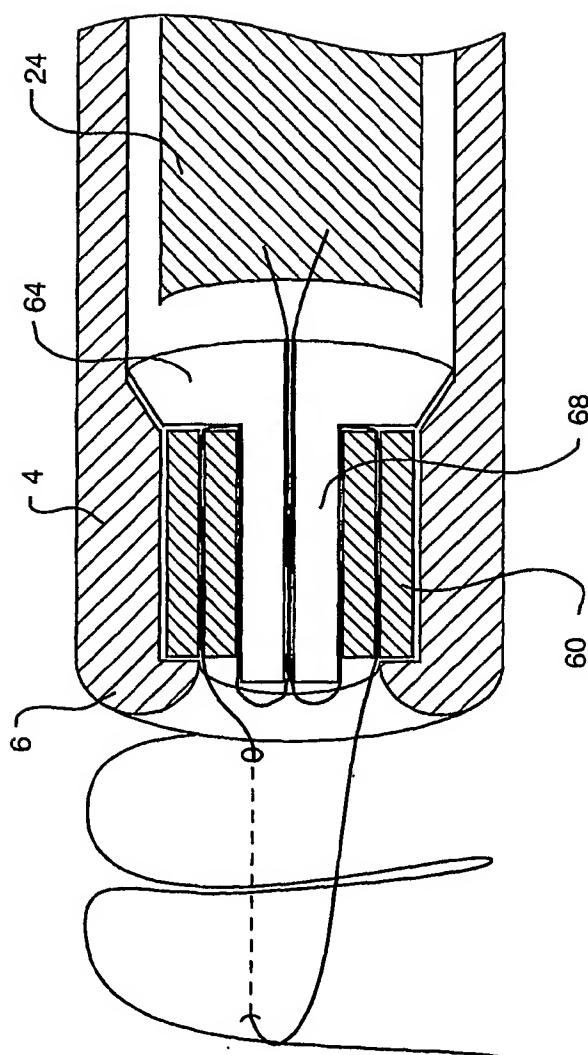


FIG. 148

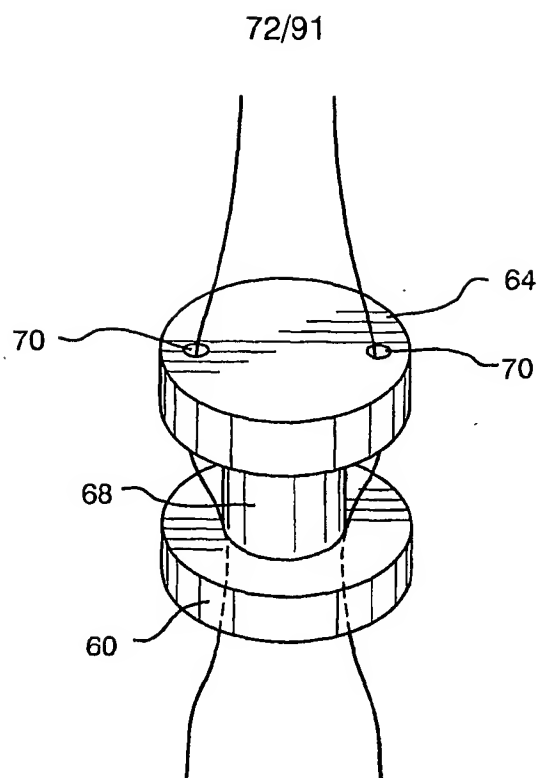


FIG. 149

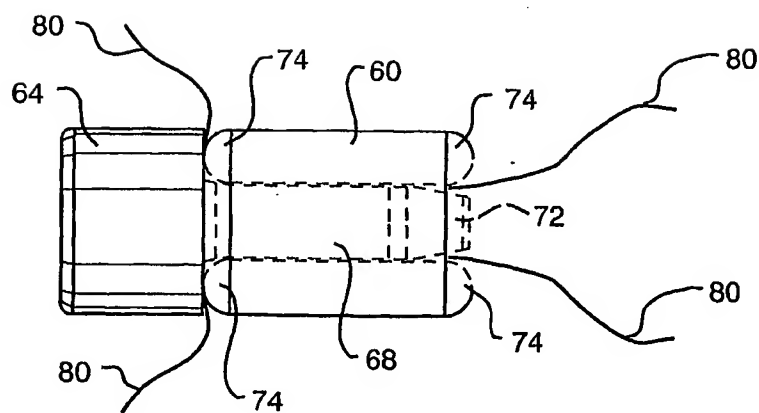
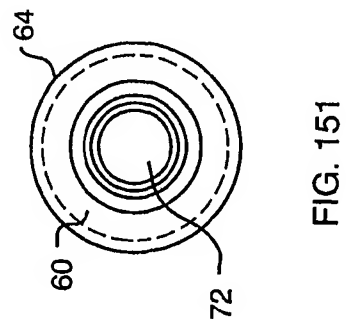
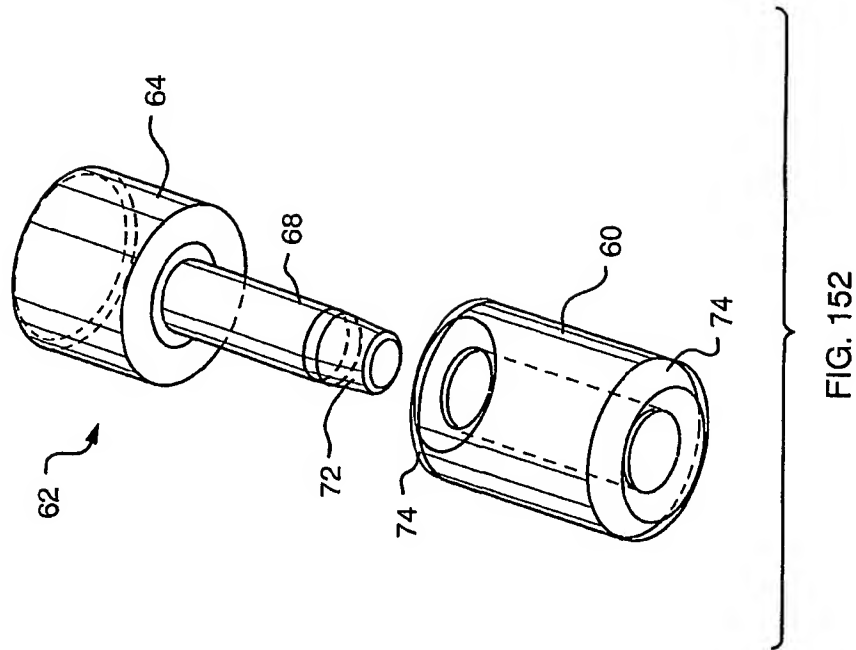


FIG. 150

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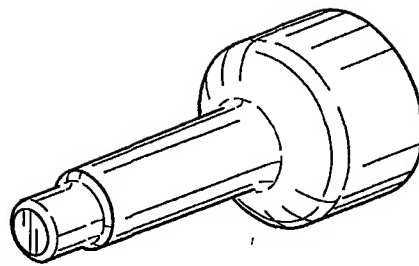


FIG. 153

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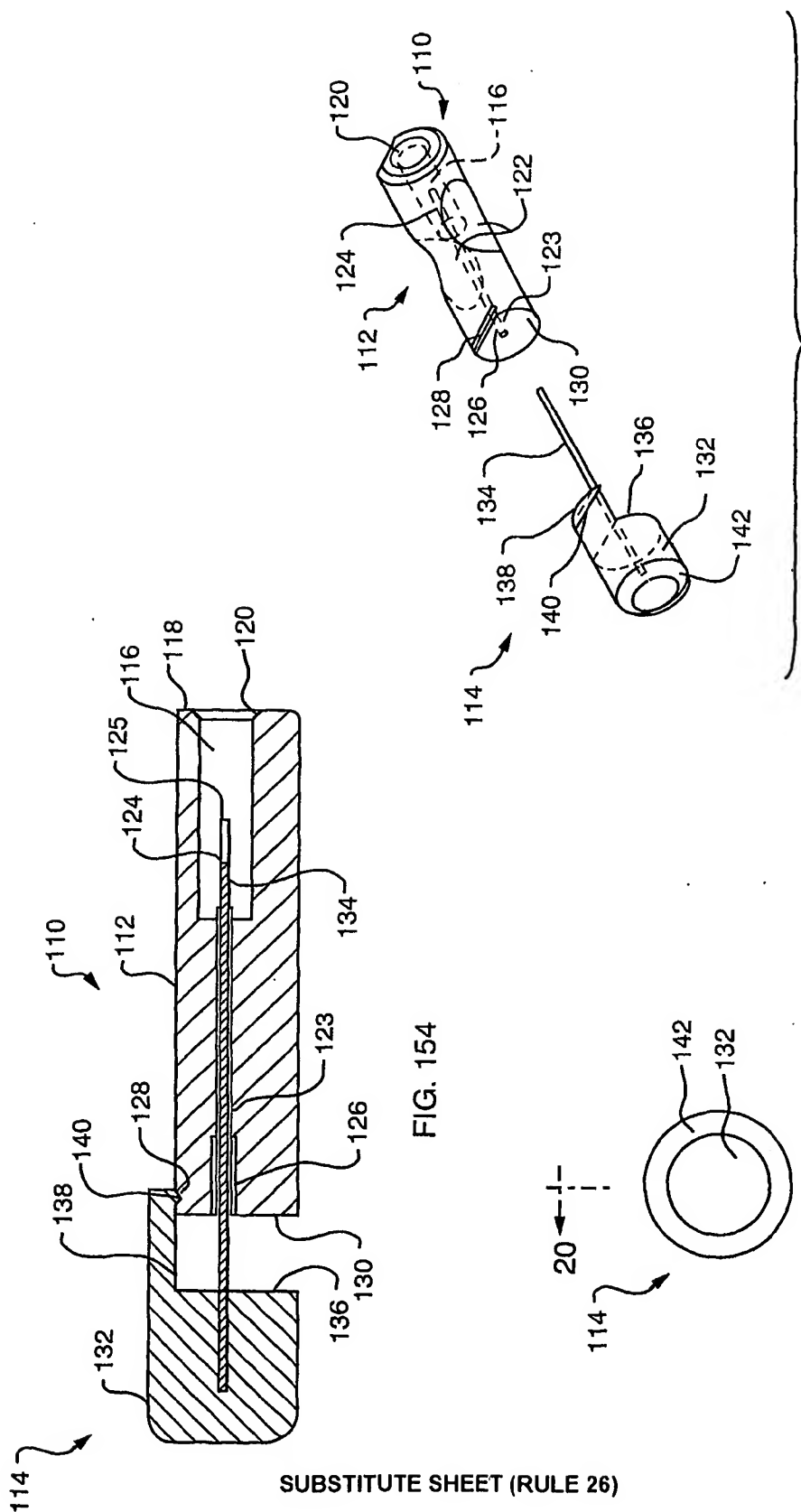


FIG. 154

FIG. 155

FIG. 156

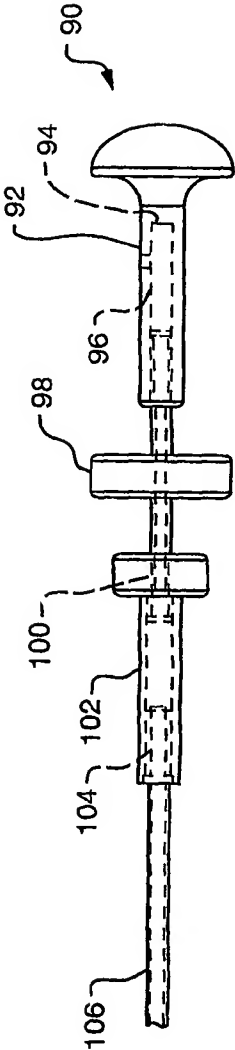


FIG. 157

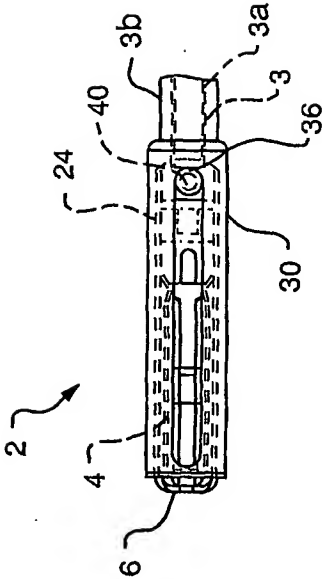


FIG. 163

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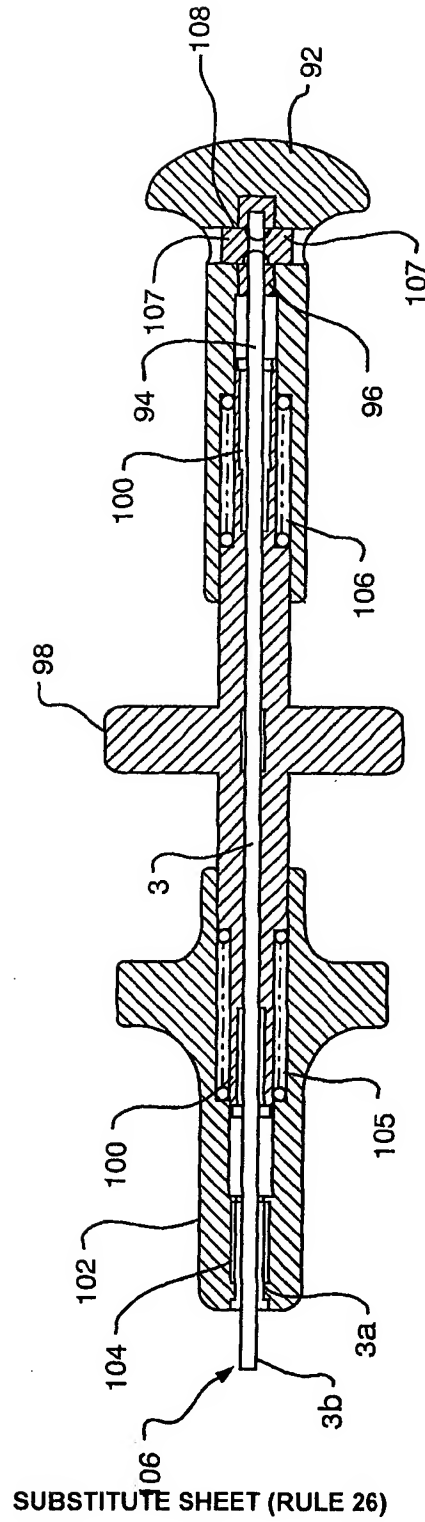


FIG. 158

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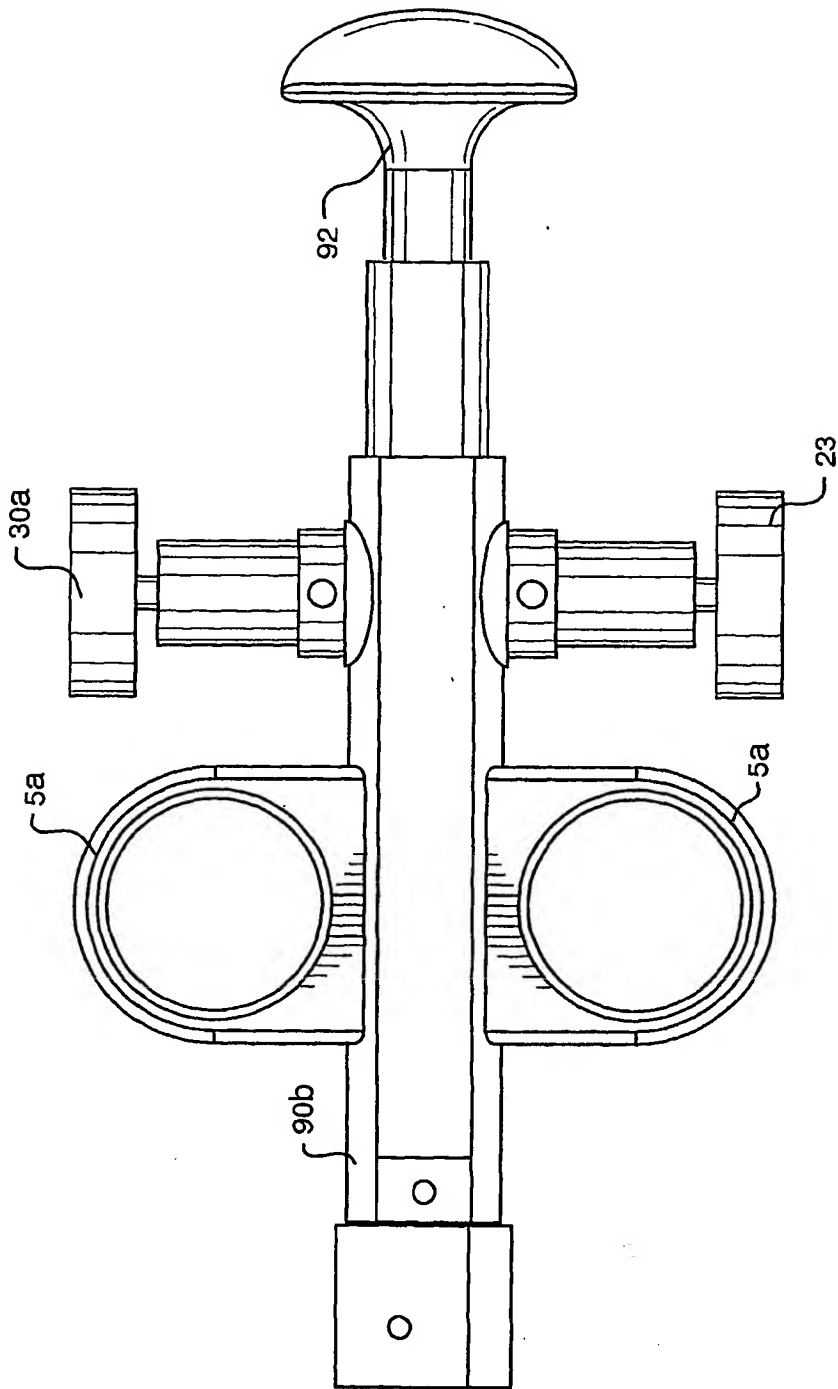


FIG. 159

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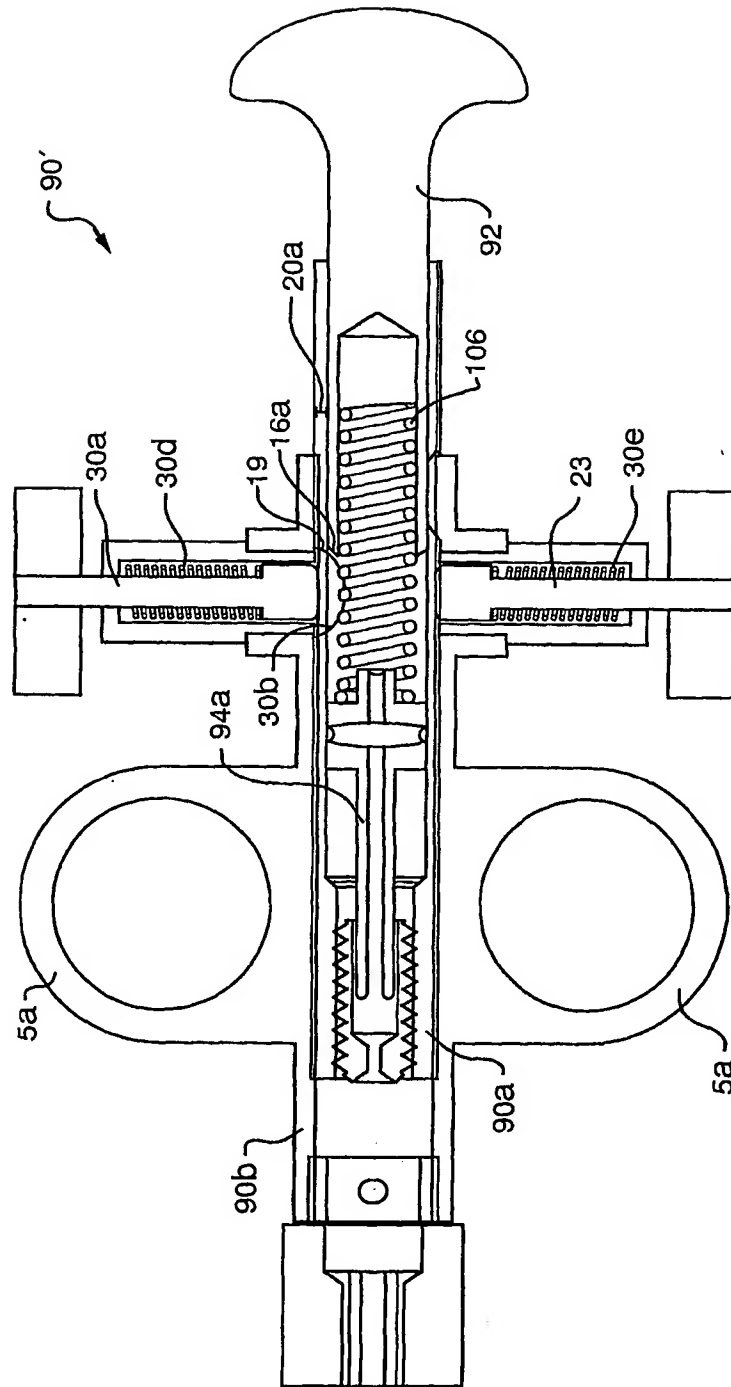


FIG. 160

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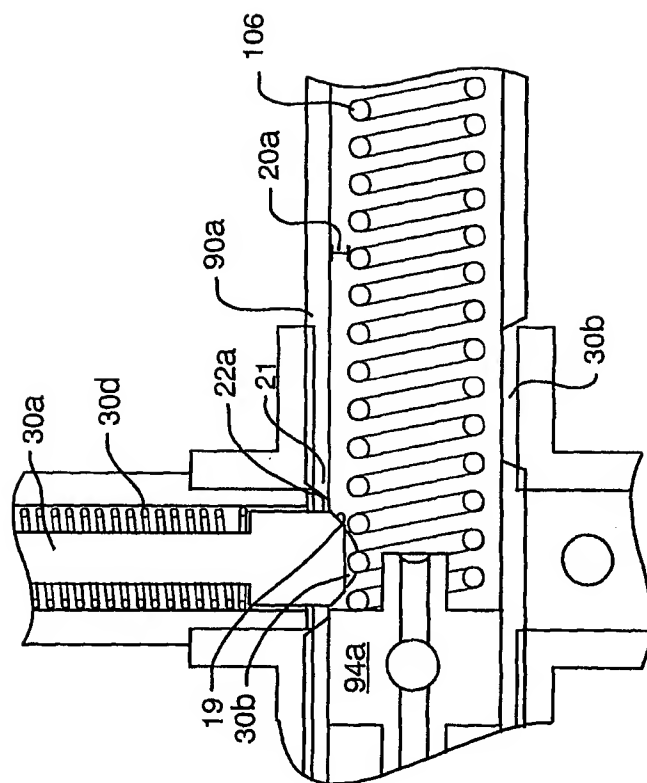


FIG. 161

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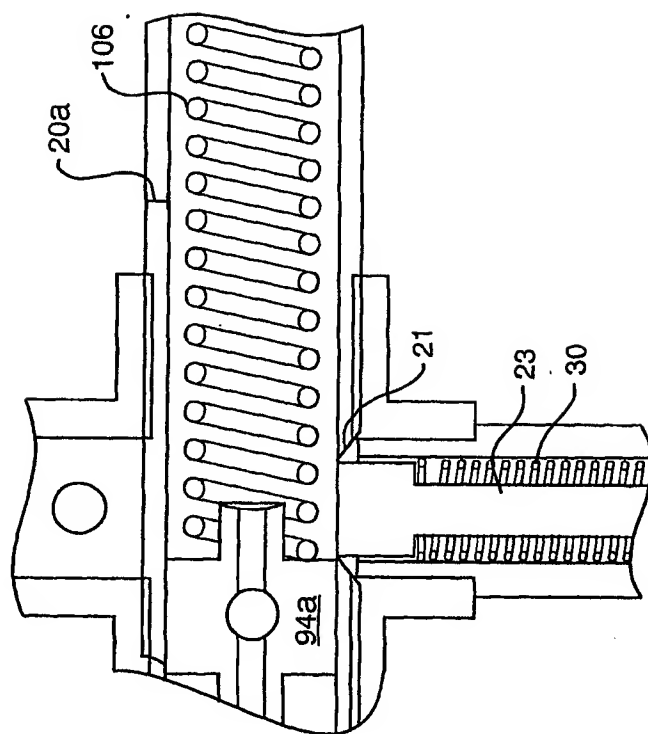


FIG. 162

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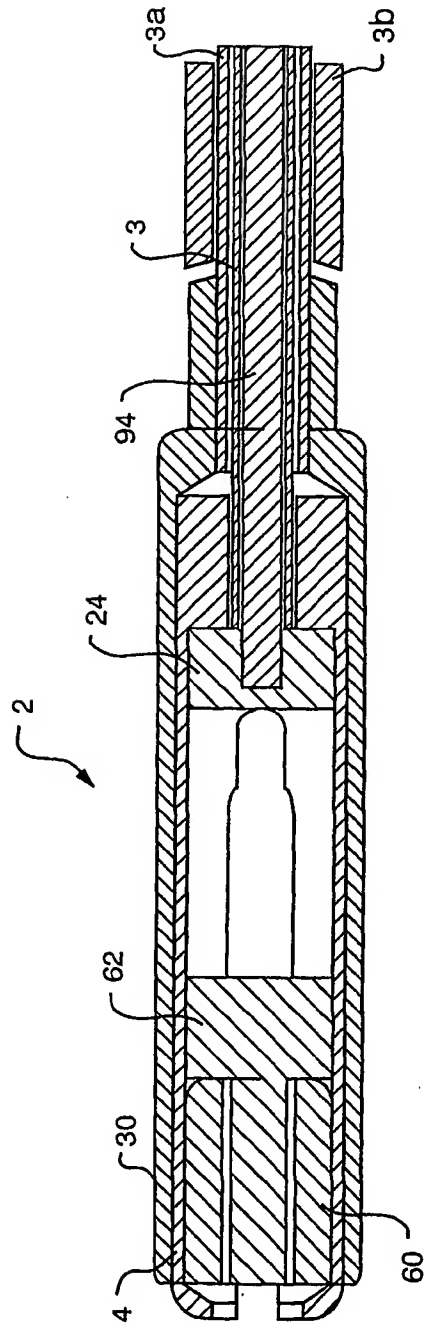


FIG. 164

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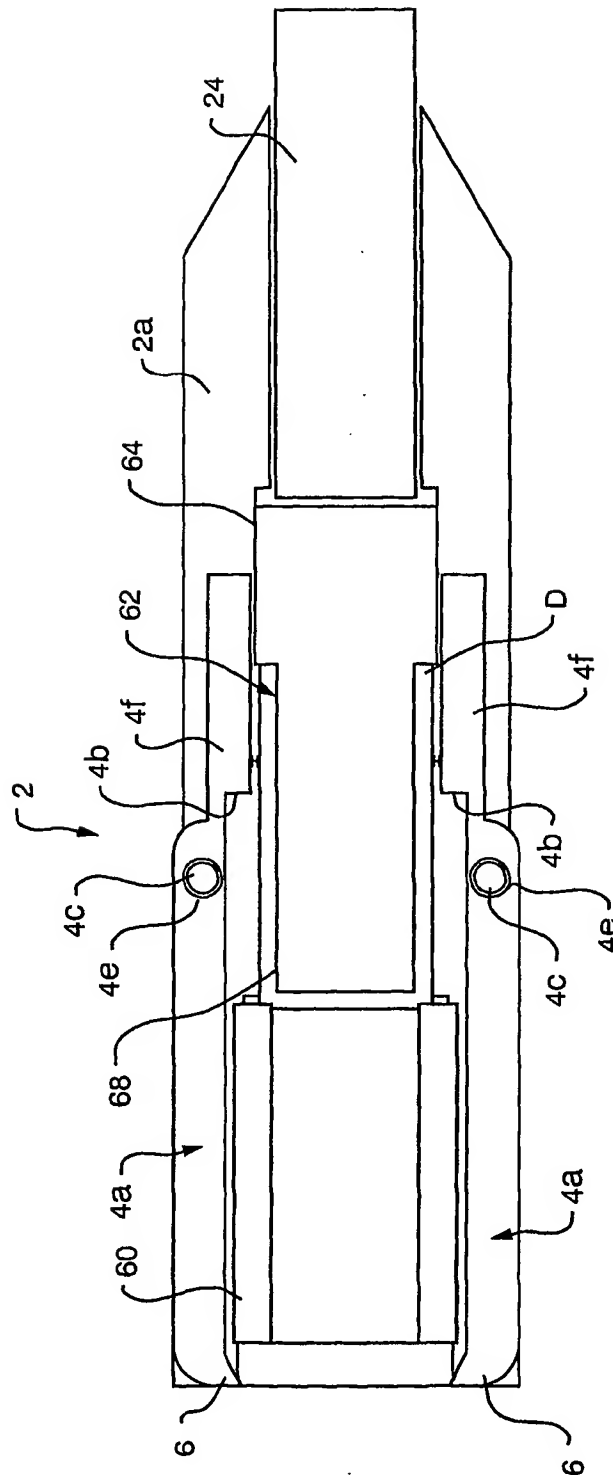


FIG. 165

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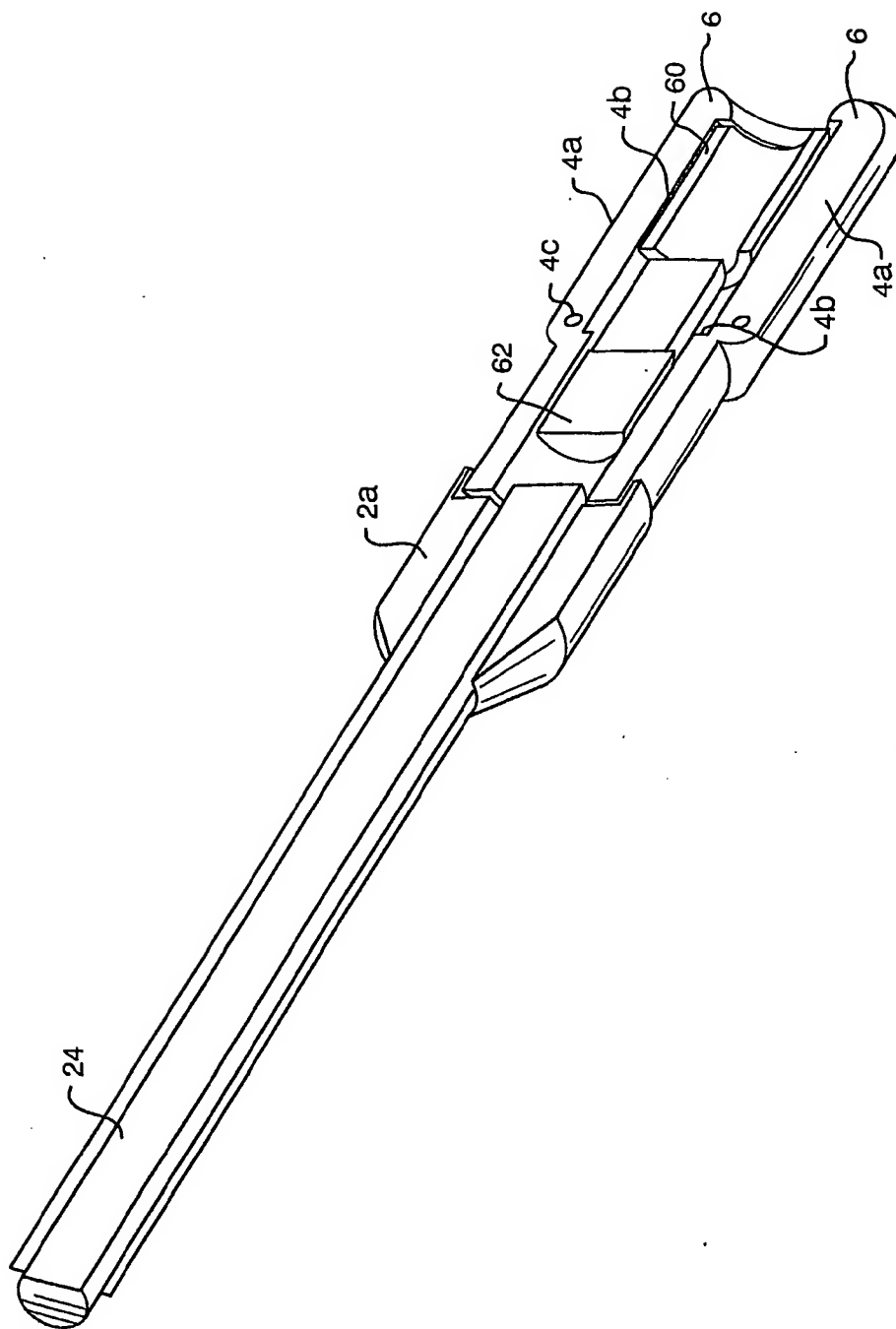


FIG. 166

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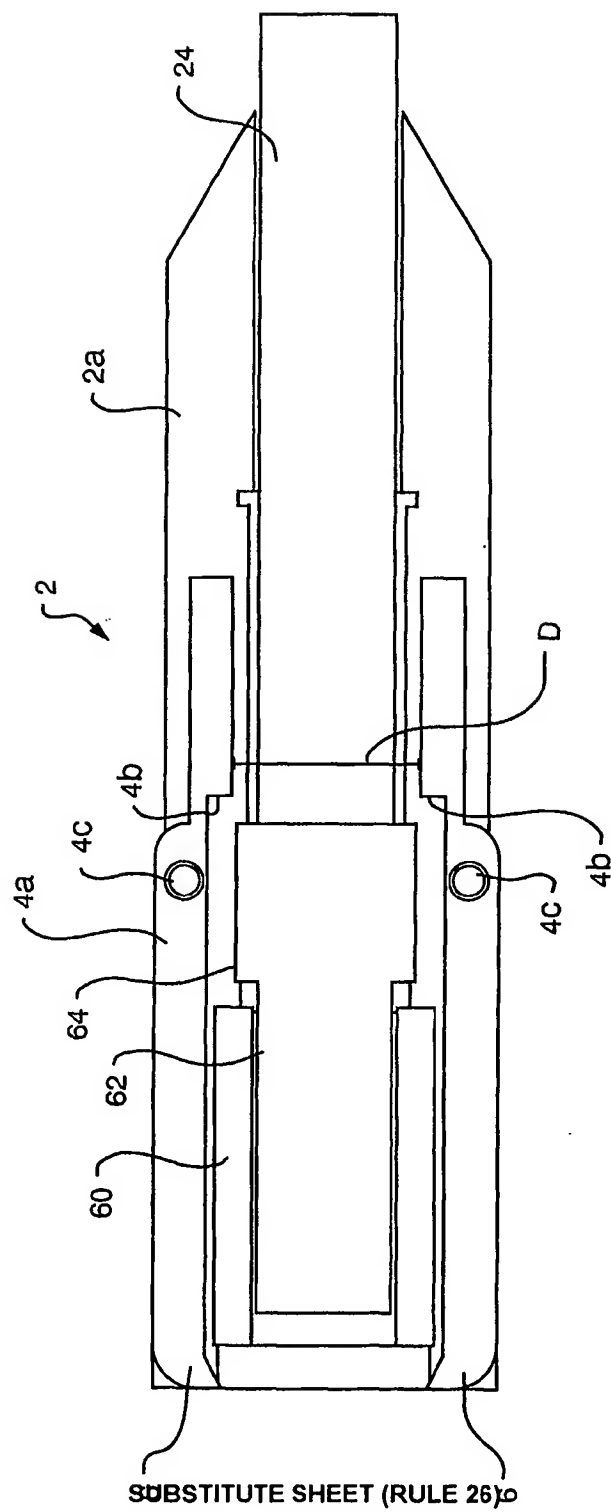


FIG. 167

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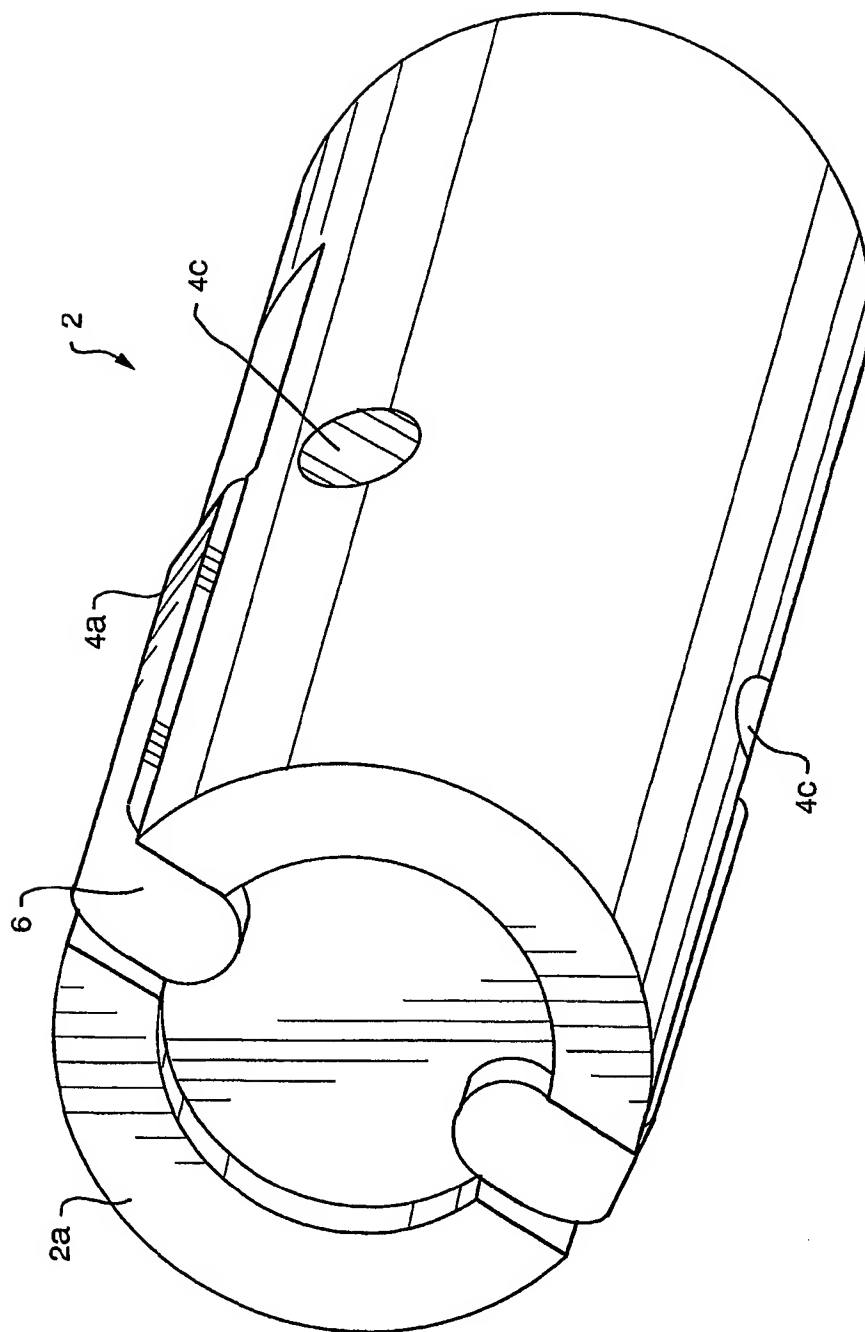


FIG. 168

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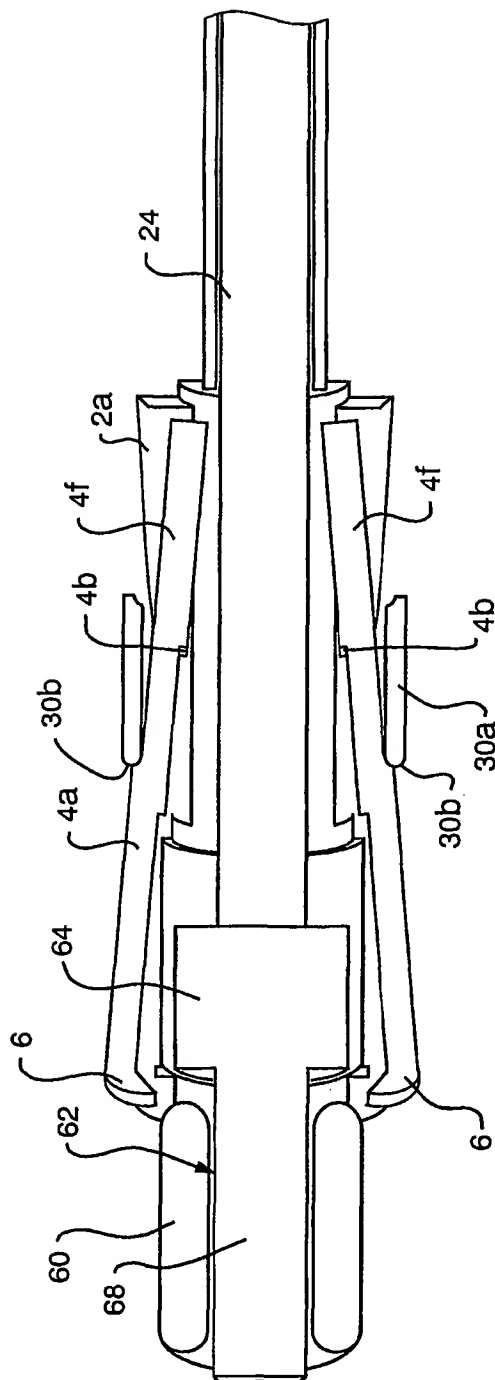


FIG. 169

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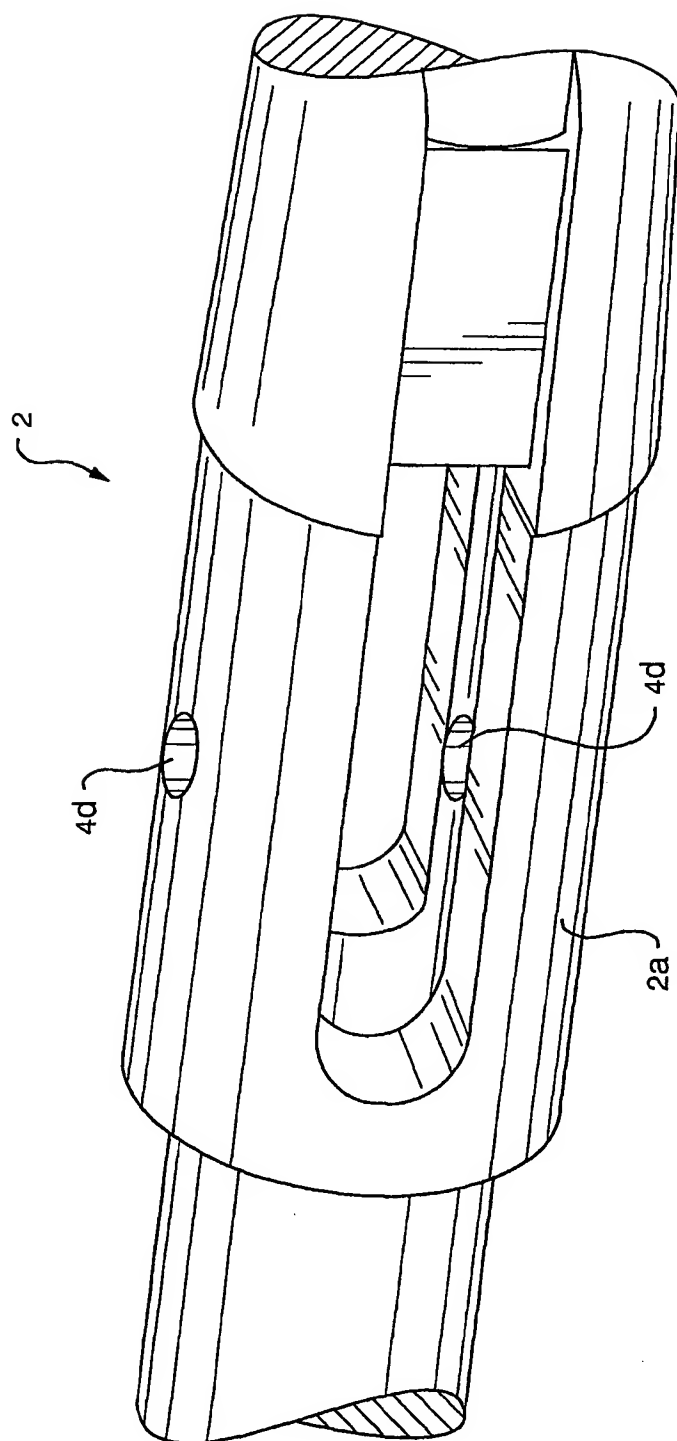


FIG. 170

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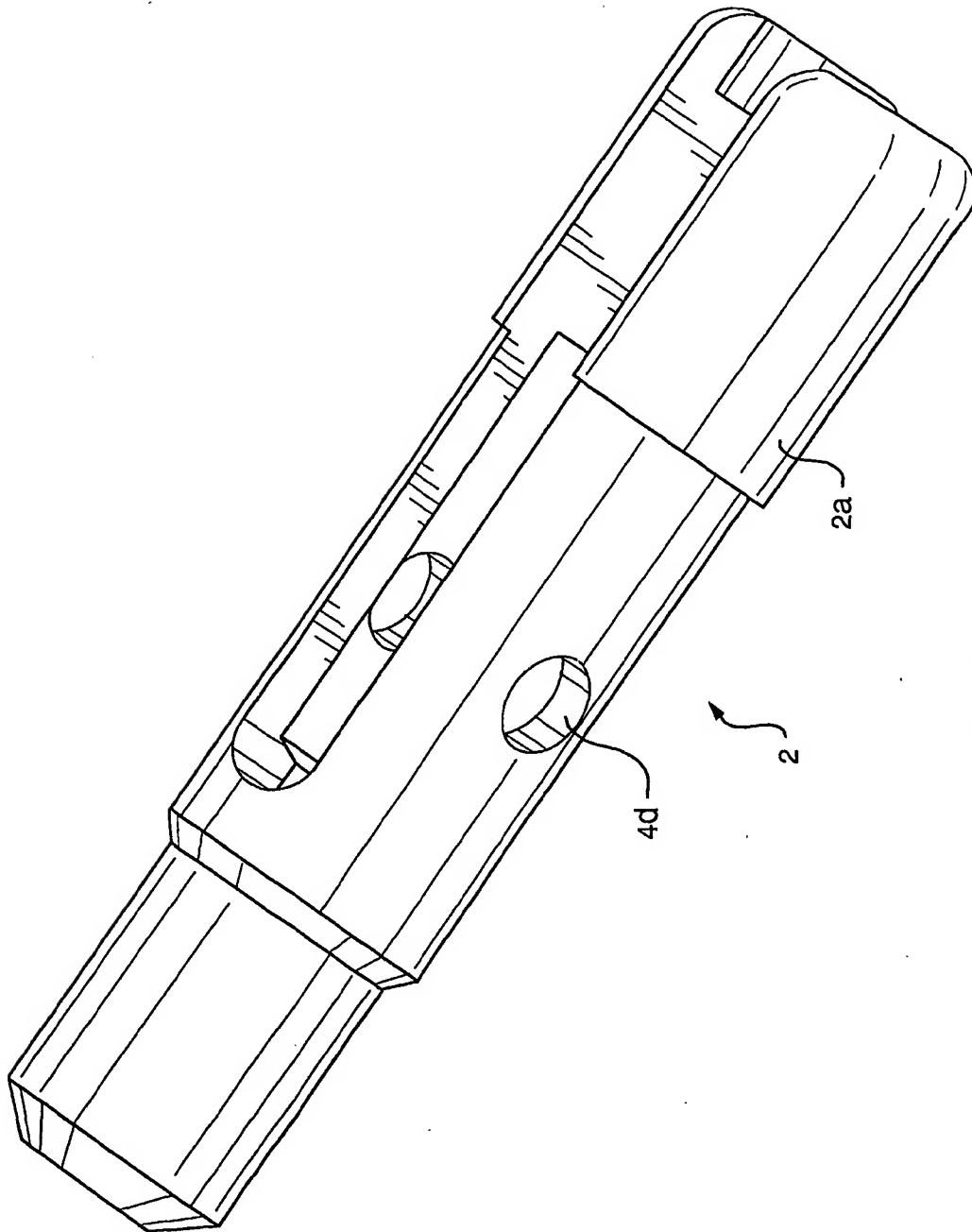


FIG. 171

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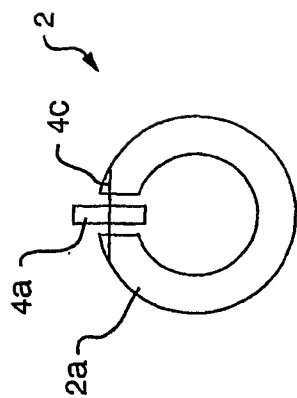


FIG. 172

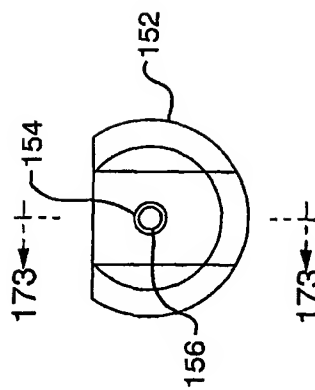


FIG. 174

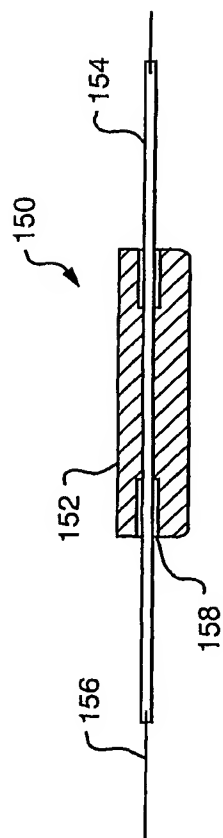


FIG. 173

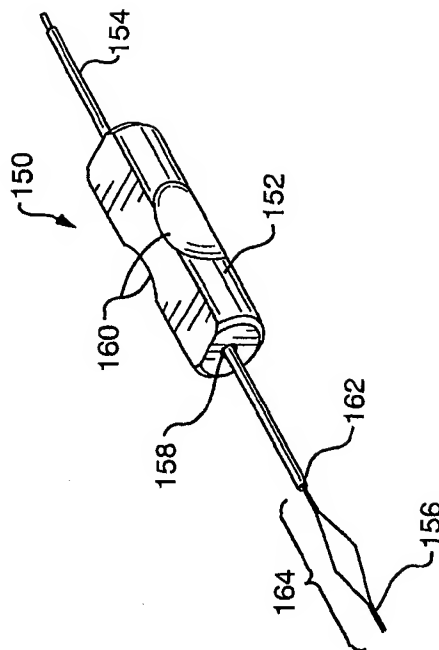
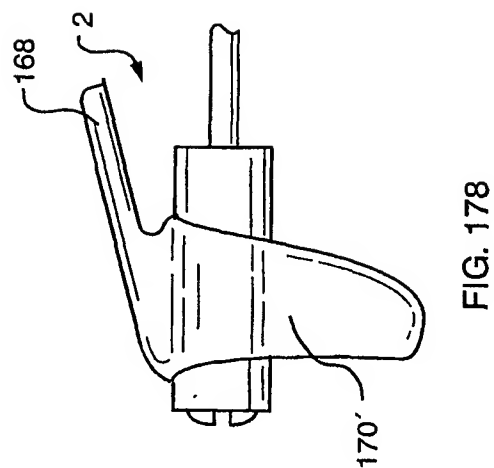
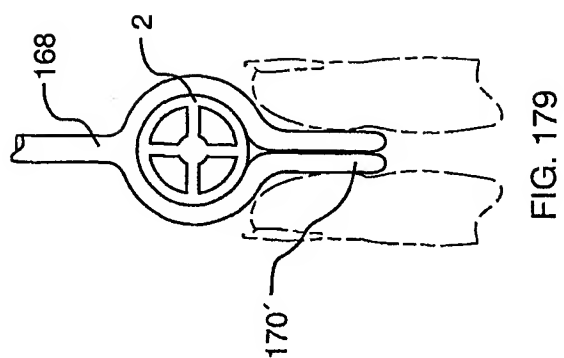
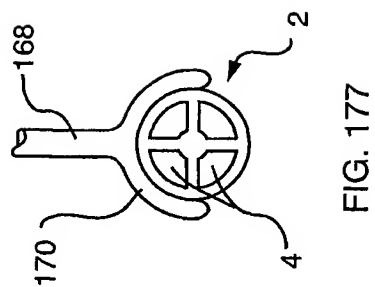
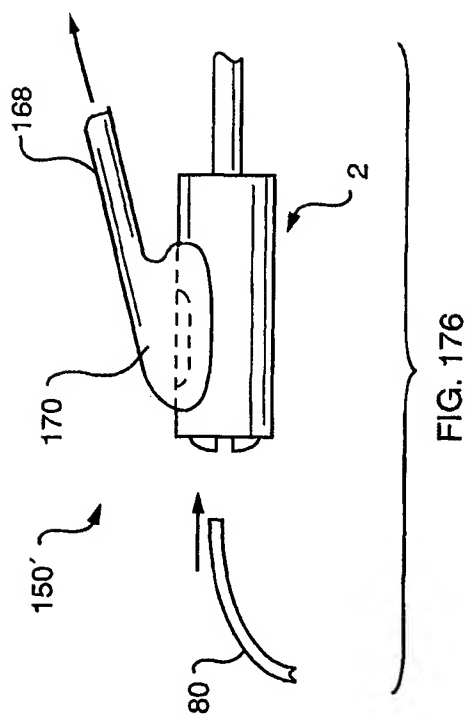


FIG. 175



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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13 September 2001 (13.09.2001)

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(10) International Publication Number
WO 01/66001 A3

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MA 01879 (US). **WEISER, Michael, F.** [US/US]; 516 Martins Pond Road, Groton, MA 01450 (US). **PAGE, Edward, Carlton** [US/US]; 359 State Road, Baldwinville, MA 01436 (US).

(21) International Application Number: PCT/US01/07349

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(74) Agent: **LORUSSO, Mark, D.**; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).

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60/205,444	19 May 2000 (19.05.2000)	US
60/253,970	29 November 2000 (29.11.2000)	US

(84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:

— with international search report

(71) Applicant (*for all designated States except US*): **C.R. BARD, INC.** [—/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

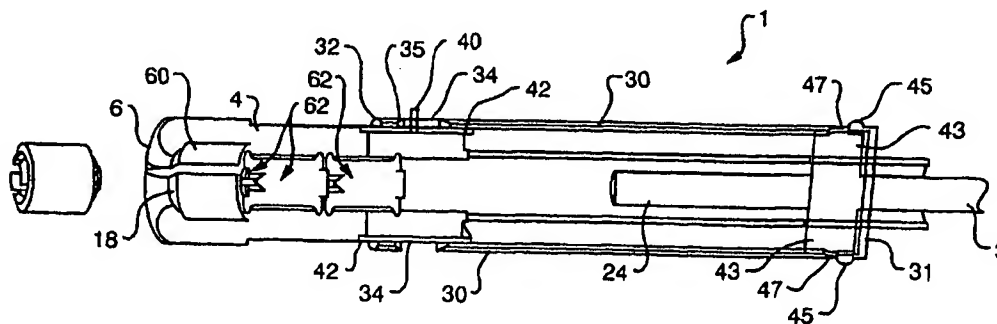
(88) Date of publication of the international search report:
20 December 2001

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **GAMBALE, Richard, A.** [US/US]; 382 Dunstable Road, Tyngsboro,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SUTURE CLIPS, DELIVERY DEVICES AND METHODS



(57) Abstract: A catheter (1) comprises a collet cage (2) with a plurality of flexible collet fingers (4) that captivate a suture clip ring (8) and a suture clip plug (3) for assembly with a suture (7). An outer sliding sleeve (30) constrains the collet fingers (4) when distally advanced to minimize potential trauma during delivery and assembly of the suture clip (3a) in close proximity to the stitched tissue. Proximal retraction of the sliding sleeve (30) coupled with the distal advancement of a pusher (24) against cam surfaces of the inner walls of the collet fingers causes the collet fingers to open. The catheter is designed to hold and assemble the suture clip (3) in a first position and release the suture clip and sever the suture ends proximal to the suture clip in a second position.

WO 01/66001 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/07349

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61B 17/04 US CL : 606/232 According to International Patent Classification (IPC) or to both national classification and IPC																				
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/232, 139, 142, 144, 151, 157, 158 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST																				
C. DOCUMENTS CONSIDERED TO BE RELEVANT																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
X — Y	US 5,514,159 A (MATULA et al.) 07 May 1996, fig. 2.	30-36																		
X —, P Y	US 6,126,677 A (GANAJA et al.) 03 October 2000, fig. 3.	30-36																		
A	US 6,001,110 A (ADAMS) 14 December 1999, whole document.	1-21																		
A	US 5,199,666 A (ORTIZ et al.) 06 April 1993, whole document.	1-21																		
A	US 5,899,921 A (CASPARI et al.) 04 May 1999, whole document.	1-21																		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"E" earlier document published on or after the international filing date</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family	"O" document referring to an oral disclosure, use, exhibition or other means			"P" document published prior to the international filing date but later than the priority date claimed		
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer LIEN NGO <i>Diane Smith f</i> Telephone No. (703) 305-0294																		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/07349

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim
A	JP 7-136177 A (ETHICON INCOPORATED) 30 MAY 1995.	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/07349

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 22-28
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Method claims

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.